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9:00 a.m.–12:30 p.m.

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Washington, DC 20002

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The President

Proclamation 8318 of November 7, 2008

World Freedom Day, 2008

By the President of the United States of America

A Proclamation

On World Freedom Day, we celebrate the anniversary of the historic fall of the Berlin Wall and honor the brave citizens of East and West Germany who helped secure freedom and liberty for future generations.

The Berlin Wall stood as a barrier that isolated the victims of imperial Communism and totalitarian power from the promise of the free world. Standing in the presence of the wall, with an unshakable belief in the power of liberty, President Ronald Reagan issued a resounding challenge on behalf of the free and the unfree alike: ''Mr. Gorbachev, tear down this wall.'' On November 9, 1989, the citizens of East Germany finally triumphed over their Communist oppressors, and the Berlin Wall came tumbling down. As the hope of freedom spread, the Soviet empire collapsed, the Iron Curtain was lifted, and Eastern and Central Europe were liberated from decades of cruel tyranny.

The Cold War demonstrated once again that freedom is precious and cannot be taken for granted, that evil is real and must be confronted, and that if they are allowed to do so, harsh rulers will subjugate others in the name of hateful ideologies. History has also proven that the transformative power of liberty overcomes this oppression. Today, many former Communist countries are using their sovereignty to aid the rise of other young democracies and to shine the light of conscience on human rights abuses. Our belief in the universality of freedom is challenged time and again, but we continue to go forward with confidence that free nations will always prevail over the enemies of liberty, peace, and justice.

On World Freedom Day, we are reminded that injustice overseas can threaten our way of life at home, and we renew our commitment to helping those who suffer under the weight of oppression.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim November 9, 2008, as World Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities, reaffirming our dedication to freedom and democracy.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of November, in the year of our Lord two thousand eight, and of the Independence of the United States of America the two hundred and thirty-third.

[FR Doc. E8–26989
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Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 915

[Docket No. AMS–FV–08–0022; FV08–915–1 FR]

Avocados Grown in South Florida; Revisions to Grade and Container Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule changes the grade and container requirements currently prescribed under the marketing order for avocados grown in South Florida (order). The order regulates the handling of avocados grown in South Florida and is administered locally by the Avocado Administrative Committee (Committee). This change establishes a minimum grade of a U.S. No. 2 for shipments within the production area, requiring these shipments to meet the same grade as currently prescribed for shipments leaving the production area. This rule also makes changes to the container and container marking requirements under the order. These changes provide a grade and a pack to meet consumer demand and improve the identification and traceability of avocado shipments.

DATES: *Effective Date:* November 13, 2008.

FOR FURTHER INFORMATION CONTACT: William G. Pimental, Marketing Specialist, or Christian D. Nissen, Regional Manager, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (863) 324–3375, *Fax:* (863) 325–8793 or *E-mail: William.Pimental@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Telephone:* (202) 720–2491, *Fax:* (202) 720–8938, or *E-mail: Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Order No. 915, as amended (7 CFR part 915), regulating the handling of avocados grown in South Florida, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule changes the grade and container requirements currently prescribed under the order. This rule establishes a minimum grade of a U.S. No. 2 for shipments within the production area, requiring these shipments to meet the same grade as currently prescribed for shipments leaving the production area. This final rule also makes changes to the container and container marking requirements established under the order. These changes provide a grade and pack to meet consumer demand and improve the identification and traceability of avocado shipments. These changes were unanimously recommended by the Committee during a number of meetings over the past several months.

Section 915.51 of the order provides, in part, the authority to issue regulations establishing specific grade and container requirements for avocados. Section 915.52 of the order provides the authority for the modification, suspension or termination of established regulations. The requisite grade and container requirements are specified under §§ 915.305 and 915.306. These sections specify, in part, the grade, container, and container marking requirements for fresh shipments of avocados grown in South Florida.

Standard containers refer to those containers specifically authorized in § 915.305(a), which can be used for shipments both inside and outside of the production area. Nonstandard containers refer to containers other than those authorized in § 915.305(a), and can only be used when shipping avocados within the production area.

This final rule makes several changes to the grade and container provisions established under the order. This rule establishes a minimum grade of a U.S. No. 2 for all avocados sold within the production area. It also requires that all nonstandard containers used for shipments within the production area be one bushel in size and that these containers be marked with the registered handler number or the name and address of the handler. This final rule also requires that all avocados sold be packed in new containers and that the containers be marked with the grade packed.

The first change establishes a minimum grade of a U.S. No. 2 for all avocados sold within the production area. Prior to this change, only avocados handled in standard containers had to meet the grade requirement of a U.S. No. 2. Avocados sold within the production area in nonstandard containers were not required to meet a minimum grade. This rule modifies § 915.306 so that all avocados sold to the fresh market in the production area, regardless of what type of container, must meet the minimum grade requirement of a U.S. No. 2.

In 1992, Hurricane Andrew decimated the Florida avocado production area leaving both avocados and containers in short supply. The industry recommended that the grade requirement be suspended for avocados sold within the production area in containers other than the standard containers defined in § 915.305. This change made more fruit available for shipment and allowed handlers to pack fruit in any obtainable container for shipment within the production area.

The industry has since recovered from the devastation caused by the hurricane. Production for the 2007–08 season was approximately 1.1 million bushels of avocados, nearly matching the level of production prior to Hurricane Andrew. However, since the grade change made following the hurricane, avocados shipped within the production area in nonstandard containers have not had to meet any specific grade requirements.

At the time of Hurricane Andrew, avocado shipments to production area markets accounted for around 12 percent of total shipments. Since that time, shipments to the production area have nearly doubled. For the last five seasons, shipments to the production area have accounted for around 23 percent of total shipments, making the production area one of the largest markets for Florida avocados.

In discussing this issue, Committee members stated that the absence of a grade requirement has resulted in poor quality avocados being offered for sale inside the production area. The past few seasons, the Committee office and members of the industry have been receiving an increasing number of negative comments regarding the quality of fruit sold in the production area. These comments indicate there is an increasing demand for higher quality fruit within the production area.

Production area produce buyers and brokers are looking for higher quality fruit to meet the demands of production area consumers. However, buyers have expressed that without a minimum grade requirement it is difficult to know the quality of the avocados being purchased. The level of quality received varies between good and poor quality. In an effort to address this issue, several handlers have already begun packing to meet a U.S. No. 2 for all their production area shipments. Still, absent a minimum grade requirement, avocados that would not meet a U.S. No. 2 are still making it to production area fresh market channels.

The Committee believes these poor quality avocados have depressed prices for better quality avocados and resulted in lower overall returns to producers. Poor quality fruit normally returns the lowest price when compared to quality fruit. Because there is no minimum grade requirement for nonstandard containers, buyers are often unsure of the level of quality they are purchasing. This tends to drive the price offered towards the lowest level for all avocados. Further, when a consumer purchases a poor piece of fruit, it can affect repurchases, reducing demand. Reduced demand also has a negative effect on price.

The Committee believes eliminating lower grade avocados from the marketplace addresses consumer demand, and helps ensure the industry is providing all their customers with a quality product. This encourages repeat purchases, which helps increase returns to producers and handlers. The Committee agreed this change will strengthen market conditions for shipments within the production area. Therefore, the Committee recommended establishing a minimum grade of a U.S. No. 2 for all avocados sold to markets within the production area.

This rule also makes changes to the container marking requirements established under the order. Prior to this action, the only container marking requirement for nonstandard containers was that the containers be marked with a Federal State Inspection Service (FSIS) lot stamp number, which is applied to an adhesive tape seal affixed to the container. While the lot stamp indicates the date the product was inspected, it does not provide any information that would identify the handler. Some handlers pay to have the adhesive tape seal preprinted with their registered handler number, and this number can be used to identify the handler. However, this is not the case for all handlers.

The Committee is concerned that the use of containers with no identifying markings poses problems with the positive identification and traceability of avocados. Such containers are almost impossible to trace back to the original handler. In cases such as marketing order compliance, it is important to be able to identify the source of avocados which are found to be in violation of order requirements. Committee members agreed that the ability to positively identify product and trace its origin is a necessity in today's marketplace. Proper handler identification on a container is an important part of this traceability.

In discussing this issue, the Committee agreed that an adhesive tape seal that is pre-printed with the registered handler number is sufficient to indicate the identity of the handler and to provide trace back. In cases where the tape seal is not printed with a registered handler number, the Committee concurred that the name and address of the handler should appear on the container. The Committee believes requiring all containers handled within the production area to be marked with a registered handler number or the name and address of the handler improve the identification and traceability of Florida avocados.

The Committee also recommended that all nonstandard containers be marked with the grade packed. Prior to this action, only standard containers were required to be marked with the grade and only from the first Monday after July 15 until the first Monday after January 1. In its discussion of this change, the Committee agreed that for nonstandard containers the grade should be marked in letters at least 3 inches in height, rather than match the 1 inch requirement for standard containers. Nonstandard containers tend to be oversized, and as such, Committee members believe the grade markings need to be in larger letters, which is more in scale with the larger containers. Also, in the production area, avocados are often displayed in the container in which they were packed. Having recommended that all avocados packed be required to meet a U.S. No. 2 to address the concerns of their customers, Committee members thought it was important that the grade be clearly displayed on the container.

Further, the Committee also agreed it was important to have the grade marked on all containers throughout the season. Therefore, the Committee recommended that the language in the rules and regulations stating that the grade only needs to appear on standard containers from the first Monday after July 15 until the first Monday after January 1 be removed, and that the grade packed be required to appear on all standard and nonstandard containers for the entire shipping season.

This rule also makes two changes to the container requirements specified under § 915.305. Before this change, there were no specific container requirements for weight and dimension for nonstandard containers, except that handlers are prohibited from using 20 bushel plastic field bins to ship avocados to markets inside the production area. As such, many different containers have been used for shipments within the production area. However, the vast majority of nonstandard containers used in the production area are new one bushel containers or used one bushel

containers that were previously packed with bananas.

The use of used banana boxes for shipping avocados within the production area increased dramatically following Hurricane Andrew, when containers were in short supply. Now, with many of the avocados sold in the production area displayed in the container in which they were packed, the Committee is concerned that the practice of packing in used containers has had a negative effect on the sale of production area avocados. These containers often have marks and stains from their previous use, and can be in poor condition. The Committee is concerned that the condition of the boxes is affecting the perception of the avocados packed inside.

With production area shipments accounting for 23 percent of total shipments, the Committee believes it is important to provide production area markets with a quality pack. The Committee believes requiring avocados to be packed in new containers is more sanitary, improves the appearance of the overall pack, and could increase sales. Consequently, the Committee recommended that all containers used to pack avocados be required to be new.

The other container change the Committee recommended was that all nonstandard containers be required to be one bushel containers. Most nonstandard containers in use are used banana boxes or new containers with dimensions similar to banana boxes. These containers hold approximately one bushel of avocados, which the industry has found to be a useful size for shipments within the production area. Rather than permitting the use of any size container within the production area, the Committee believes requiring the use of a one bushel container provides some additional uniformity to the pack.

With many handlers already utilizing the one bushel container for production area shipments, this sized container is readily available throughout the production area. Also, because all containers to be used are now required to be new, and handlers will be purchasing containers, the Committee believes this is a good time to establish requirements for nonstandard containers. Requiring all nonstandard containers to be one bushel provides for a uniform pack that is attractive to the consumer. Therefore, the Committee recommended that one bushel containers be used for all shipments within the production area.

These changes to the grade and container requirements improve the overall quality and pack, which meets the demands of production area customers. Responding to market preferences is expected to benefit producers and handlers of Florida avocados. Further, requiring container marking requirements improves the identification and traceability of production area avocados. Consequently, the Committee recommended the above changes to the rules and regulations under the order.

This final rule also makes a minor correction to § 915.306(a)(1). This change removes language which only pertained to the period November 2, 1992, through March 31, 1993. This language is obsolete, and as such is no longer necessary.

Section 8e of the Act provides that when certain domestically produced commodities, including avocados, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. This final rule does not change the minimum grade of a U.S. No. 2 established for avocados shipped outside the production area or the maturity requirements established under the order. This rule just requires all avocados shipped within the production area to meet the same minimum grade of a U.S. No. 2, and changes the container requirements under the domestic handling regulation. Consequently, no corresponding changes to the import regulations are required.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 35 handlers of Florida avocados subject to regulation under the order and approximately 300 producers of avocados in the production area. Small agricultural service firms, which include avocado handlers, are defined by the Small Business Administration (SBA) as those whose annual receipts are less than $7,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

According to Committee data, the average price for Florida avocados during the 2007–08 season was around $12.00 per 55-pound bushel container, and total shipments were near 1.1 million 55-pound bushels. Using the average price and shipment information provided by the Committee, the majority of avocado handlers could be considered small businesses under SBA's definition. In addition, based on avocado production, producer prices, and the total number of Florida avocado producers, the average annual producer revenue is less than $750,000. Consequently, the majority of avocado handlers and producers may be classified as small entities.

This final rule revises the grade and container requirements currently prescribed under the order. This rule establishes a minimum grade of a U.S. No. 2 for shipments within the production area, requiring these shipments to meet the same grade as currently prescribed for shipments leaving the production area. It also requires that all nonstandard containers used for shipments within the production area be one bushel in size and that these containers be marked with the registered handler number or the name and address of the handler. This final rule also requires that all avocados sold be packed in new containers and that the containers be marked with the grade packed. These changes provide a grade and pack to meet consumer demand, which will increase producer returns. This rule also improves the identification and traceability of production area avocados. This rule revises §§ 915.305 and 915.306, which specify the requisite grade and container requirements. Authority for these actions is provided in §§ 915.51 and 915.52 of the order. These changes were unanimously recommended by the Committee during a number of meetings over the past several months.

This final rule could result in some additional costs. These potential costs stem primarily from the application of the minimum grade to nonstandard containers, the new container marking requirements, and the requirement that all containers packed be new containers.

The grade requirement for nonstandard containers could result in the loss of some sales, as handlers will no longer be able to sell fruit not meeting a U.S. No. 2 inside the production area. However, these losses are expected to be minimal. Several handlers have already started packing their nonstandard containers to meet a

U.S. No. 2 in response to consumer demand. Further, the volume of fruit failing to meet a U.S. No. 2 represents only a small percentage of production area shipments. The Committee estimates lower grade avocados account for only around 6 percent of production area shipments. Last year, the industry shipped nearly 264,000 55-pound containers to production area markets. Using these numbers, lower grade avocados accounted for only 15,840 of the containers shipped to the production area last year, or 1 percent of total industry shipments. Consequently, this rule is not expected to appreciably impact the total number of shipments.

Further, the grade change is not expected to result in perceptibly higher inspection costs. Currently, all avocados shipped in the production area must meet maturity requirements regardless of the container in which they are packed. Consequently, all avocados are already inspected, so any increase in inspection costs will be minimal.

The costs associated with the recommended changes in marking requirements are also expected to be nominal. Larger operations use automated stamping, and already print necessary information on standard containers. A small reconfiguration would allow them to meet this requirement. Some operations order their containers preprinted with the needed information. As this rule requires the use of new containers, handlers will be purchasing containers. The added cost of the additional marking requirements for preprinted containers should be minor. Smaller operations stamp the containers by hand. These operations will be able to meet the new requirements with a one-time purchase of a grade stamp and a name and address stamp.

This rule could also result in a slight increase in cost for handlers that were using used containers. However, Committee members stated that plain, one bushel containers are readily available on the market at reasonable prices. Also, dealers collect and sell the used containers, so used containers are not cost free. Further, the available quantities of used containers are not sufficient to handle all production area shipments; so many new nonstandard containers are already being purchased. Consequently, the cost associated with this change should also be minimal.

While this rule could result in some additional costs, the changes are expected to have a positive effect in the marketplace. The production area is an important market for the industry, accounting for nearly 23 percent of shipments for the last five seasons. The availability of poor quality avocados has had a price depressing effect on the market. Without change, there could be a continued erosion of market confidence and producer returns.

Requiring nonstandard containers to meet the minimum grade of a U.S. No. 2 addresses consumer demand and helps protect the production area market from the price depressing effects of poor quality avocados. In addition, requiring all production area avocados to be packed in new containers clearly marked with the grade packed also improves the overall avocado pack sold in the production area. These new requirements allow handlers to respond to market preferences which are expected to benefit producers and handlers of Florida avocados. Consumers also benefit as a result of the higher quality pack available in the marketplace. This rule also provides improved traceability and identification of Florida avocados. Consequently, the benefits of this rule outweigh the potential costs associated with these changes. The costs and benefits of this rule are not expected to be disproportionately different for small or large entities.

The Committee discussed alternatives to these changes. One alternative considered was to not make any changes to the rules and regulations. However, the Committee agreed making these changes makes the industry more responsive to consumer demand. It also provides for better identification and traceability of production area avocados. Therefore, this alternative was rejected. The Committee also considered the alternative of requiring the grade to be stamped on nonstandard containers in letters and numbers at least 1 inch in height as is required for standard containers. However, with nonstandard containers being larger in size and with production area avocados sold in the container, the Committee determined that the grade should be clearly visible, and that 1 inch was not large enough. Therefore, this alternative was also rejected.

This final rule revises the grade and container requirements currently prescribed under the avocado marketing order. Accordingly, this action will not impose any additional reporting or recordkeeping requirements on either small or large avocado handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule. In addition, the Committee's meetings were widely publicized throughout the avocado industry and all interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the August 8, 2007, September 9, 2007, January 9, 2008, and February 13, 2008, meetings were public meetings and all entities, both large and small, were able to express views on these issues.

A proposed rule concerning this action was published in the **Federal Register** on September 23, 2008 (73 FR 54740). Copies of the rule were mailed or sent via facsimile to all Committee members and avocado handlers. Finally, the rule was made available through the Internet by USDA and the Office of the Federal Register. A 15-day comment period ending October 8, 2008, was provided to allow interested persons to respond to the proposal. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because handlers are already shipping Florida avocadoes from the 2008–2009 crop. Further, handlers are aware of this rule, which was recommended at a public meeting. Also, a 15-day comment period was provided for in the proposed rule.

List of Subjects in 7 CFR Part 915

Avocados, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 915 is amended as follows:

PART 915—AVOCADOS GROWN IN SOUTH FLORIDA

■ 1. The authority citation for 7 CFR part 915 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Two new paragraphs (d) and (e) are added to § 915.305 to read as follows:

§ 915.305 Florida Avocado Container Regulation 5.

* * * * *

(d) Avocados handled for the fresh market in containers other than those authorized under § 915.305(a) and shipped to destinations within the production area must be packed in 1-bushel containers.

(e) All containers in which the avocados are packed must be new, and clean in appearance, without marks, stains, or other evidence of previous use.

3. In § 915.306, paragraphs (a)(1), (a)(6) and (a)(7) are revised to read as follows:

§ 915.306 Florida avocado grade, pack, and container marking regulation.

(a) * * *

(1) Such avocados grade at least U.S. No. 2, except that avocados handled to destinations within the production area may be placed in containers with avocados of dissimilar varietal characteristics.

* * * * *

(6) Such avocados when handled in containers authorized under § 915.305, except for those to export destinations, are marked once with the grade of fruit in letters and numbers at least 1 inch in height on the top or one side of the container, not to include the bottom.

(7) Such avocados when handled in containers other than those authorized under § 915.305(a) for shipment to destinations within the production area are marked once with the grade of fruit in letters and numbers at least 3 inches in height on the top or one side of the container, not to include the bottom. Each such container is also to be marked at least once with either the registered handler number assigned to the handler at the time of certification as a registered handler or with the name and address of the handler.

* * * * *

Dated: November 5, 2008.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. E8–26855 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Docket No. AMS–FV–08–0044; FV08–981–1 FIR]

Almonds Grown in California; Relaxation of Incoming Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim final rule relaxing the incoming quality control requirements prescribed under the California almond marketing order (order). The order regulates the handling of almonds grown in California and is administered locally by the Almond Board of California (Board). This rule continues in effect the action that changed the date by which almond handlers must satisfy their inedible disposition obligation from August 31 to September 30 of each year. This change provides handlers more flexibility in their operations in light of larger almond crops.

DATES: *Effective Date:* December 12, 2008.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Kurt J. Kimmel, Regional Manager, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (559) 487–5901, *Fax:* (559) 487–5906, or *E-mail: Terry.Vawter@usda.gov* or *Kurt.Kimmel@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Telephone:* (202) 720–2491, *Fax:* (202) 720–8938, or *E-mail: Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

USDA is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule continues in effect a relaxation of the incoming quality control requirements prescribed under the order by changing the date by which almond handlers must satisfy their inedible disposition obligation from August 31 to September 30 of each year. This provides handlers more flexibility in their operations in light of larger almond crops.

Section 981.42 of the order provides authority for a quality control program. Paragraph (a) of this section requires handlers to obtain incoming inspections on almonds received from growers to determine the percent of inedible kernels in each lot of any variety. Inedible kernels are poor quality kernels or pieces of kernels as defined in § 981.408. A handler's inedible disposition obligation is based on the percentage of inedible kernels in lots received by such handler during a crop year, as determined by the Federal-State inspection service. Handlers must satisfy their obligation by disposing of inedible kernels and other almond material in Board-accepted, non-human consumption outlets like oil and animal feed. Section 981.42(a) also provides

authority for the Board, with approval of the Secretary, to establish rules and regulations necessary to administer this program.

Prior to publication of the interim final rule, § 981.442(a)(5) of the order's administrative rules and regulations specified that handlers must satisfy their inedible disposition obligation no later than August 31 succeeding the crop year in which the obligation was incurred. The crop year runs from August 1 through July 31.

Since the mid-1990's, almond crops have doubled in size and are now over 1 billion pounds annually. Larger crops have resulted in larger quantities of inedible kernels. Between the 1993–94 and 1997–98 crop years, almond production averaged about 570 million pounds and inedible disposition obligations averaged about 7 million pounds annually. Between the 2003–04 and 2007–08 crop years, production averaged about 1 billion pounds and inedible disposition obligations averaged about 10 million pounds annually.

Many handlers now operate year-round and dispose of their inedible kernels at one time after the end of the crop year. With larger crops, it has become difficult for handlers to meet the August 31 inedible-disposition deadline because of the larger volume of inedible kernels that must be disposed of under the program. Thus, the Board recommended extending the deadline from August 31 to September 30, giving handlers an additional month to meet their prior year's obligation. This provides handlers more flexibility in their operations in light of larger almond crops. The revision of § 981.442(a)(5) continues in effect, accordingly.

This rule also continues in effect the removal of obsolete language in § 981.442(a)(5). That section was modified in 2006 to specify that at least 50 percent (increased from 25 percent) of a handler's crop year inedible disposition obligation must be satisfied with dispositions consisting of inedible kernels. The 50 percent requirement does not apply to handlers with total inedible obligations of less than 1,000 pounds. However, that section still contained the sentence referencing the 25 percent requirement. This rule continues in effect both the removal of that sentence and the revision of § 981.442(a)(5), accordingly.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 6,200 producers of almonds in the production area and approximately 100 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $6,500,000.

Data for the 2006–07 crop year indicate that about 50 percent of the handlers shipped under $6,500,000 worth of almonds. Dividing average almond crop value for 2006–07 reported by the National Agricultural Statistics Service of $2.258 billion by the number of producers (6,200) yields an average annual producer revenue estimate of about $364,190. Based on the foregoing, about half of the handlers and a majority of almond producers may be classified as small entities.

This rule continues in effect both the revision and relaxation of § 981.442(a)(5) of the order's administrative rules and regulations, whereby handlers are permitted to satisfy their inedible disposition obligation no later than September 30 of each year for obligations incurred in the previous crop year, rather than the previous deadline of August 31 of each year. This rule also continues in effect the removal of an obsolete sentence in that section that referenced handler dispositions containing 25 percent inedible kernels. Authority for this action is provided in § 981.42(a) of the order.

Regarding the impact of this action on affected entities, extending the disposition deadline provides handlers with additional flexibility in light of larger almond crops. Handlers who operate year round and dispose of their inedible kernels at one time after the end of the crop year have an additional month to satisfy their prior year's inedible obligation.

The Board considered alternatives to this action. The Board's Food Quality and Safety Committee (committee) met in September and November 2007 and discussed the difficulties that handlers were experiencing with meeting the August 31 disposition deadline. The committee recommended revising the regulation to allow July dispositions to be counted towards either the current year or the following year's obligation. However, the intent of the inedible program is to ensure that poor quality almonds from the current crop year are removed from the market. Thus, allowing July dispositions to count towards the following year's obligation would not meet the intent of the program.

The committee deliberated on this issue again in April 2008. The committee considered the option of extending the August 31 deadline to September 30. The Board concurred with this option at its meeting on April 2, 2008, and referred the issue back to the committee for full discussion. The committee met again on April 22, 2008, to discuss the potential change. Ultimately, the committee recommended this option to the Board, and the Board subsequently unanimously recommended this change at its May 2008 meeting.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large almond handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, as noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Further, the committee and Board meetings where this issue was discussed were widely publicized throughout the almond industry and all interested persons were invited to attend the meetings and encouraged to participate in Board deliberations. Like all committee and Board meetings, the meetings held in September and November 2007, and in April and May 2008 were all public meetings and all entities, both large and small, were able to express their views on this issue.

An interim final rule concerning this action was published in the **Federal Register** on July 24, 2008. Copies of the rule were provided to all Board members and almond handlers by the

Board's staff. In addition, the rule was made available through the Internet by USDA and the Office of the Federal Register. That rule provided for a 60-day comment period which ended on September 22, 2008. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrders SmallBusinessGuide.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the Board's recommendation, and other information, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** on July 24, 2008 (73 FR 43056), will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

PART 981—ALMONDS GROWN IN CALIFORNIA

■ Accordingly, the interim final rule amending 7 CFR part 981, which was published at 73 FR 43056 on July 24, 2008, is adopted as a final rule without change.

Dated: November 5, 2008.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. E8–26851 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 611

RIN 1901–AB25

Advanced Technology Vehicles Manufacturing Incentive Program

AGENCY: Office of the Chief Financial Officer, Department of Energy (Department or DOE).

ACTION: Interim final rule; request for comment.

SUMMARY: Today's interim final rule establishes the Advanced Technology Vehicles Manufacturing Incentive Program authorized by section 136 of the Energy Independence and Security Act of 2007, as amended. Section 136 provides for grants and loans to eligible automobile manufacturers and component suppliers for projects that reequip, expand, and establish manufacturing facilities in the United States to produce light-duty vehicles and components for such vehicles, which provide meaningful improvements in fuel economy performance beyond certain specified levels. Section 136 also provides that grants and loans may cover engineering integration costs associated with such projects. This interim final rule establishes applicant eligibility and project eligibility requirements for both the grant and the loan program. Today's interim final rule also establishes the application requirements and the general terms for the loan program. At present, Congress has appropriated funds through the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, for only the loan program. As such, DOE will be implementing the loan program only at this time, though issuing rules for both the grant and loan programs.

DATES: This interim final rule is effective November 12, 2008. Applications for a direct loan will be reviewed by DOE in tranches. To be eligible for the first tranche, applications may be submitted or hand delivered to the Postal Mail address listed in **ADDRESSES** until December 31, 2008. The deadline for loan applications for subsequent tranches of loans will be the end of every calendar quarter thereafter as funds and available loan authority permit. Comments must be received by DOE no later than December 12, 2008. If you submit information that you believe to be exempt by law from public disclosure, you should submit one complete copy, as well as one copy from which the information claimed to be exempt by law from public disclosure has been deleted. DOE is responsible for the final determination with regard to disclosure or nondisclosure of the information and for treating it accordingly under the DOE Freedom of Information regulations at 10 CFR 1004.11.

ADDRESSES: You may submit comments, identified by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: ATVMLoan@hq.doe.gov.*
- *Postal Mail:* Advanced Technology Vehicles Manufacturing Incentive Program, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.
- *Hand Delivery/Courier:* Advanced Technology Vehicles Manufacturing Incentive Program, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

Instructions: All submissions must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Lachlan Seward, Advanced Technology Vehicles Manufacturing Incentive Program, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, 202–586–8146; or Daniel Cohen, Assistant General Counsel for Legislation and Regulatory Law, Office of the General Counsel, 1000 Independence Avenue, SW., Washington, DC 20585, 202–586–2918.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background
II. Discussion of Interim Final Rule
A. Applicant Eligibility for Grant and Loan Programs—Statutory Criteria
B. Applicant Eligibility for Direct Loan Program—Secretarial Determinations
C. Project Eligibility for Grant and Loan Programs
D. Terms for Direct Loans
E. Application Process for Direct Loan Program
F. Credit Subsidy Cost for Direct Loans
G. Project Costs
H. Assessment of Fees for Direct Loan Program
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I. Introduction and Background

Section 136 of the Energy Independence and Security Act of 2007 (''EISA''), enacted on December 19, 2007, Public Law 110–140, authorizes the Secretary of Energy (''Secretary'') to make grants and direct loans to eligible applicants for projects that reequip, expand, or establish manufacturing facilities in the United States to produce qualified advanced technology vehicles, or qualifying components and also for

engineering integration costs associated with such projects.

On September 30, 2008, President Bush signed into law the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009. (Pub. L. 110–329; ''Continuing Resolution, 2009''). Section 129(a) of the Continuing Resolution, 2009, appropriated $7,500,000,000 for the ''Advanced Technology Vehicles Manufacturing Loan Program Account'' for the cost of direct loans as authorized by EISA section 136(d) and states that commitments for direct loans using such amount shall not exceed $25,000,000,000 in total loan principal, and $10 million for DOE's administrative expenses for implementing the program.

Further, section 129(c) of the Continuing Resolution, 2009, also made several substantive amendments to section 136. Specifically, section 136 was amended to provide:

1. That the Department will pay the full credit subsidy cost of the loans;
2. The Department with limited flexibility from the general rules applicable to the hiring of Federal staff and consultants necessary to administer the program; and
3. That, not later than 60 days after enactment of the Continuing Resolution, 2009, the Secretary shall promulgate an interim final rule establishing regulations that the Secretary deems necessary to administer section 136 and any loans made by the Secretary pursuant thereto.

By directing the Department to issue an interim final rule, Congress required the Department to issue a rule without having first issued a proposed rule for public comment. Though under no obligation to accept public comment prior to issuance, the Department received comments at a series of meetings it held with a variety of stakeholders. The comments received at those meetings were considered in the development of this interim final rule. A list of the meetings held and the written comments that were received can be viewed at: *http://www.atvmloan.energy.gov*. Through publication of this interim final rule, the Department is also providing a comment period until December 12, 2008. Comments submitted during this period will be reviewed and a final rule, responding to those comments as well as reflecting the experience the Department gains in implementing this interim final rule, will be issued at a later date.

Today's interim final rule establishes regulations necessary to implement the loan and grant programs authorized by section 136 of EISA, as amended by the Continuing Resolution, 2009 (hereinafter referred to as ''section 136''). Additionally, concurrent with the release of today's interim final rule, the Department is announcing that applications for the first tranche of loans must be submitted to the Department on or before the effective date of today's interim final rule. The deadline for loan applications for subsequent tranches of loans will be every 90 days thereafter as funds and available loan authority permit.

II. Discussion of the Interim Final Rule

Section 136 authorizes the Secretary to issue grants and direct loans to applicants for the costs of reequipping, expanding, or establishing manufacturing facilities in the United States to produce qualified advanced technology vehicles, or qualifying components. Section 136 also authorizes the Secretary to issue grants and direct loans for the costs of engineering integration performed in the United States of qualifying advanced technology vehicles and qualifying components. Section 136 sets forth certain specific conditions pertaining to the grant and direct loan programs, but also leaves to the Secretary's discretion the interpretation of other criteria. This interim final rule sets forth eligibility criteria, application procedures, outlines specific terms and conditions for the receipt of grants and direct loans, and sets forth interpretations of other provisions that section 136 requires the Department to address.

Section 136 defines ''advanced technology vehicle'' as a ''light duty vehicle that meets—(A) the Bin 5 Tier II emission standard established in regulations issued by the Administrator of the Environmental Protection Agency under section 202(i) of the Clean Air Act (42 U.S.C. 7521(i)), or a lower-numbered Bin emission standard; (B) any new emission standard in effect for fine particulate matter prescribed by the Administrator under that Act (42 U.S.C. 7401 *et seq.*); and (C) at least 125 percent of the average base year combined fuel economy for vehicles with substantially similar attributes.''

Section 136 defines the term ''qualifying components'' to mean ''components that the Secretary determines to be—(A) designed for advanced technology vehicles; and (B) installed for the purpose of meeting the performance requirements of advanced technology vehicles.''

Section 136 defines ''engineering integration costs'' to include the cost of engineering tasks relating to ''(A) incorporating qualifying components into the design of advanced technology vehicles; and (B) designing tooling and equipment and developing manufacturing processes and material suppliers for production facilities that produce qualifying components or advanced technology vehicles.''

In today's interim final rule DOE adopts several definitions and provisions contained in the corporate average fuel economy (CAFE) regulations established by the National Highway Traffic Safety Administration (NHTSA) (codified at 49 CFR Parts 523–538). DOE recognizes that NHTSA has proposed to amend some of these definitions and provisions, in part, in response to EISA. *See*, 73 FR 24352; May 2, 2008. It is anticipated that any amendments to the CAFE definitions that may result from NHTSA issuing a final rule will not impact the regulations established in today's interim final rule. However, if necessary, DOE may amend, in a future rulemaking document, today's interim final rule in response to future amendments to the CAFE regulations.

A. Applicant Eligibility for Grant and Direct Loan Programs—Statutory Criteria

Section 136, as amended, directs the Secretary to establish ''regulations that the Secretary deems necessary to administer this section and any loans made by the Secretary pursuant to this section.'' The statute requires the Department's regulations to establish eligibility requirements for both the grant and direct loan programs. To that end, section 136 lays out specific criteria for the Secretary to use to determine an applicant's eligibility, and directs the Secretary to make other determinations relating to eligibility prior to issuance of any loan or award of any grant.

Section 136 contains a requirement that the Department promulgate regulations regarding eligibility of automobile manufacturers. There is no similar statutory eligibility requirement for component manufacturers. With regard to automobile manufacturers, section 136 requires the Department's regulations to establish that

> [I]n order for an automobile manufacturer to be eligible for an award or loan under this section during a particular year, the adjusted average fuel economy of the manufacturer for light duty vehicles produced by the manufacturer during the most recent year for which data are available shall be not less than the average fuel economy for all light duty vehicles of the manufacturer for model year 2005.

(42 U.S.C. 17013(e))

To determine the relevant fuel economy baselines for a new manufacturer or for a manufacturer that has not previously produced equivalent vehicles, the statute allows the Secretary to substitute industry averages. (42 U.S.C. 17013(e))

Today's interim final rule establishes the regulations necessary to determine whether an automobile manufacturer meets the minimum fuel economy improvement threshold. If the applicant is an automobile manufacturer that manufactured vehicles in model year (MY) 2005 that were subject to the CAFE standards (existing manufacturers), that manufacturer must demonstrate that the fuel economy of its vehicle fleet (the manufacturer's passenger and light-duty truck fleets) for the most recent MY that data are available is no less than the fuel economy of its MY 2005 fleet.

The statute requires that an existing manufacturer's MY 2005 average fuel economy is to be compared to the adjusted average fuel economy of that manufacturer's light-duty fleet from the most recent year for which there is available data, but the statute does not specify which data. DOE interprets the ''most recent year for which data are available'' to mean the most recent model year for which a manufacturer has final data for the purpose of compliance with the fuel economy standards for passenger automobiles (49 CFR Part 531) and light trucks (49 CFR Part 533).[1] By relying on the most recent MY for which final CAFE compliance data are available, the fuel economy comparison for existing manufacturers will be based on data approved by the U.S. Environmental Protection Agency (EPA) under 10 CFR Part 600.[1]

Section 136 directs that this fuel economy comparison is to be based on an adjusted average fuel economy. Although the statute does not define ''adjusted average fuel economy,'' DOE, for purposes of today's interim final rule, has defined ''adjusted average fuel economy'' to mean a harmonic production weighted average of the combined fuel economy, as determined under the Energy Policy and Conservation Act (Pub. L. 94–163; ''EPCA''), as amended, of the vehicles within a manufacturer's vehicle fleet. In MY 2005, there was a CAFE standard applicable to vehicles defined as passenger automobiles[2] and a CAFE standard applicable to vehicles defined as light trucks.[3] The adjusted average fuel economy combines a manufacturer's passenger automobile fleet and light truck fleet, measured in miles per gallon (mpg).

The fuel economy improvement threshold for eligibility specified in section 136(e) requires that automobile manufacturers applying under either the loan or grant program demonstrate a history of maintaining or improving the fuel economy of its fleet. Consistent with section 136, DOE is requiring that an existing manufacturer demonstrate that the fuel economy of its passenger automobile and light duty truck fleet is at least as efficient as that manufacturer's MY 2005 fleet.

To demonstrate compliance with the fuel economy level as required by subsection (e) of section 136, the adjusted average fuel economy of an existing automobile manufacturer's MY 2005 passenger automobile and light truck fleet is compared to the adjusted average fuel economy of that manufacturer's passenger automobile and light truck fleet for the most recent year in which final CAFE compliance data are available. The adjusted average fuel economy of an existing automobile manufacturer's fleet in the most recent year for which CAFE compliance data are available must be no less than the adjusted average fuel economy of that manufacturer's fleet in MY 2005.

For example, if in MY 2005 a manufacturer produced vehicles as follows:

Model	MPG	Production volume
Passenger Automobile A	27	150,000
Light Truck B	20	200,000
Light Truck C	17	100,000

the adjusted average fuel economy for that manufacturer in MY 2005 would be calculated as:

$$\frac{Total\ Production\ Volume}{\frac{\#\ VehicleA}{FuelEconomy} + \frac{\#\ VehicleB}{FuelEconomy} + \frac{\#\ VehicleC}{FuelEconomy}}, \text{ or}$$

$$\frac{450,000}{\frac{150,000}{27} + \frac{200,000}{20} + \frac{100,000}{17}} = 20.99 \text{ MPG}$$

In this example, the manufacturer's adjusted fuel economy average for the most recent year, at time of application, for which CAFE compliance data are available, must be no less than 20.99 mpg. Otherwise the manufacturer would not be eligible for a section 136 grant award or direct loan.

[1] Compliance with the fuel economy standards is based on data approved by EPA. (*See*, 49 CFR 537.9).

[2] ''Passenger automobile'' is defined for the purpose of CAFE as essentially any 4-wheeled vehicle propelled by fuel which is manufactured primarily for use on public roads, is rated at 10,000 pounds gross vehicle weight or less, is manufactured primarily for the use in the transportation of 10 or fewer individuals, and is not a ''light truck.'' (*See*, 42 FR 38362, July 28, 1977, as amended at 43 FR 12013, March 23, 1978; 44 FR 4493, Jan. 2, 1979)

[3] ''Light truck'' is defined for the purpose of the CAFE requirements, as

(a) an automobile other than a passenger automobile which is either designed for off-highway operation, as described in paragraph (b) of this section, or designed to perform at least one of the following functions:

(1) Transport more than 10 persons;

(2) Provide temporary living quarters;

(3) Transport property on an open bed;

(4) Provide greater cargo-carrying than passenger-carrying volume; or

(5) Permit expanded use of the automobile for cargo-carrying purposes or other nonpassenger-carrying purposes through the removal of seats by means installed for that purpose by the automobile's manufacturer or with simple tools, such as screwdrivers and wrenches, so as to create a flat, floor level surface extending from the forward most point of installation of those seats to the rear of the automobile's interior.

(b) An automobile capable of off-highway operation is an automobile—

(1)(i) That has 4-wheel drive; or

(ii) Is rated at more than 6,000 pounds gross vehicle weight; and

(2) That has at least four of the following characteristics [ ]—

(i) Approach angle of not less than 28 degrees.

(ii) Breakover angle of not less than 14 degrees.

(iii) Departure angle of not less than 20 degrees.

(iv) Running clearance of not less than 20 centimeters.

(v) Front and rear axle clearances of not less than 18 centimeters each.

(*See*, 42 FR 38362, July 28, 1977, as amended at 43 FR 12013, Mar. 23, 1978; 58 FR 18029, Apr. 7, 1993).

If an automobile manufacturer is a new manufacturer, or has not previously produced ''equivalent vehicles'' (new automobile manufacturer), section 136 permits the Secretary to base the fuel economy improvement comparison on ''industry averages.'' Section 136 does not define ''new manufacturer''' nor does it define ''equivalent vehicles.'' Based on the statute's specification of MY 2005 as the MY against which the fuel economy is compared, DOE interprets ''new manufacturer'' to mean a manufacturer that did not manufacture vehicles in MY 2005 that were subject to the CAFE standards.

Further, section 136 does not define the term ''equivalent vehicles.'' The comparison for new automobile manufacturers is in terms of ''equivalent vehicles,'' which indicates a comparison at a level other than the fleet wide comparison required for existing manufacturers, i.e., a comparison of ''light duty vehicles produced by the manufacturer.'' However, use of ''equivalent vehicles'' in section 136(e) does not indicate that the fuel economy comparison should be at a level as narrow as the comparison between vehicles with ''substantially similar attributes'' as the statute specifies for criteria in determining whether a vehicle is an ''advanced technology vehicle.'' DOE interprets ''equivalent vehicle'' to mean a vehicle within the same class as is defined for the purpose of CAFE compliance, i.e., a passenger automobile or a light truck.

For a new automobile manufacturer, eligibility under subsection (e) of section 136 is based on the fuel economy of the vehicle or vehicles that are the subject of the application. The projected combined fuel economy of the vehicles that are the subject of the application must be at least equal to the adjusted average fuel economy for all vehicles that were in the same vehicle class as the subject vehicles in MY 2005. It is likely that a new manufacturer will not have CAFE compliance data for a vehicle that is the subject of an application. In demonstrating the projected combined fuel economy of a vehicle for CAFE compliance data are not available, a new manufacturer must rely on a peer reviewed model (e.g., the Powertrain System Analysis Toolkit© (PSAT) [4]). A new automobile manufacturer is eligible if the demonstrated combined fuel economy of the subject vehicle is at least as efficient as the industry average for that vehicle class in MY 2005.

As noted above, an applicant that is a manufacturer of a qualifying component does not need to make a showing of improved fuel economy for the purpose of threshold applicant eligibility for a section 136 grant or loan. However, a component manufacturer will be required to demonstrate the contributions to fuel economy improvements of the qualifying component that is the subject of the grant or loan application. The necessary demonstration of a qualifying component's improvement to fuel economy is discussed later in this document.

B. Applicant Eligibility for Direct Loan Program—Secretarial Determinations

Section 136 directs the Secretary to make certain determinations with regard to applicants for direct loans. First, the Secretary must determine that the applicant is ''financially viable without the receipt of additional Federal funding associated with the proposed project [.]'' In today's interim final rule, the Department interprets the term ''financially viable'' to mean that an applicant must demonstrate a reasonable prospect that the Applicant will be able to make payments of principal and interest on the loan as and when such payments become due under the terms of the loan documents, and that the applicant has a net present value which is positive, taking all costs, existing and future, into account. Determining whether an applicant has met this criterion is a decision committed by law to the Secretary. In making that determination, today's regulations provide that the Secretary will consider a number of factors, including, but not limited to:

(1) The applicant's debt-to-equity ratio as of the date of the loan application;

(2) The applicant's earnings before interest, taxes, depreciation, and amortization (EBITDA) for the applicant's most recent fiscal year prior to the date of the loan application;

(3) The applicant's debt to EBITDA ratio as of the date of the loan application;

(4) the applicant's interest coverage ratio (calculated as EBITDA divided by interest expenses) for the applicant's most recent fiscal year prior to the date of the loan application;

(5) the applicant's fixed charge coverage ratio (calculated as EBITDA plus fixed charges divided by fixed charges plus interest expenses) for the applicant's most recent fiscal year prior to the date of the loan application;

(6) the applicant's liquidity as of the date of the loan application;

(7) statements from applicant's lenders that the applicant is current with all payments due under loans made by those lenders at the time of the loan application; and

(8) financial projections demonstrating the applicant's solvency through the period of time that the loan is outstanding.

As stated in section 136, the Secretary must find that the loan recipient is financially viable without ''additional Federal funding associated with the proposed project.'' In today's interim final rule, the Department interprets the term ''additional Federal funding'' to mean any loan, grant, guarantee, insurance, payment, rebate, subsidy, credit, tax benefit, or any other form of direct or indirect assistance from the Federal government, or any agency or instrumentality thereof, other than the proceeds of a loan approved under section 136, that is, or is expected to be made available with respect to, the project or activities for which the loan is sought under section 136, and is to be received by the applicant after entering into an Agreement with DOE.

Section 136 also requires the Secretary to ensure that the proceeds of the direct loan are expended ''efficiently and effectively.'' The Secretary will carry out this obligation by reviewing documents required in 611.109 for purposes of loan monitoring and audit. Loan funds will be considered as being expended ''efficiently and effectively'' if that documentation demonstrates, in the sole judgment of the Secretary, that the borrower is making appropriate progress toward achieving the purpose for which the loan was originally made. The Department anticipates that in order to meet this requirement, loan proceeds will be disbursed through periodic drawdowns that correspond to actual project expenses.

Section 136 also requires applicants to submit to the Secretary written assurance that ''(A) all laborers and mechanics employed by contractors or subcontractors during construction, alteration, or repair that is financed, in whole or in part, by a loan under this section shall be paid wages at rates not less than those prevailing on similar construction in the locality, as determined by the Secretary of Labor in accordance with sections 3141–3144, 3146, and 3147 of title 40, United States Code; and (B) the Secretary of Labor shall, with respect to the labor standards described in this paragraph, have the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (5 U.S.C. App.) and section 3145 of title 40, United States Code.'' Accordingly, section 611.101(m) of

[4] See, *http://www.transportation.anl.gov/modeling_simulation/PSAT/index.html.*

today's interim final rule requires applicants to submit this required assurance as part of any direct loan application.

C. Project Eligibility for Grant and Loan Programs

Under section 136, grants and direct loans may be provided for the costs of reequipping, expanding, or establishing manufacturing facilities in the United States to produce qualified advanced technology vehicles, or qualifying components. Section 136 also authorizes the Secretary to issue grants and direct loans for the costs of engineering integration performed in the United States of qualifying advanced technology vehicles and qualifying components. Specifically, subsection (b) of section 136 directs that for the grant program [5]—

The Secretary shall provide facility funding awards under this section to automobile manufacturers and component suppliers to pay not more than 30 [6] percent of the cost of—

(1) reequipping, expanding, or establishing a manufacturing facility in the United States to produce—

(A) qualifying advanced technology vehicles; or

(B) qualifying components; and

(2) engineering integration performed in the United States of qualifying vehicles and qualifying components.

(42 U.S.C. 17013(b))

Under the loan provisions of section 136, the Secretary is directed ''to provide a total of not more than $25,000,000,000 in loans to eligible individuals and entities (as determined by the Secretary) for the costs of activities described in subsection (b).'' (42 U.S.C. 17013(d)(1)). Section 136 provides two categories of projects eligible for direct loans: (1) Manufacturing facilities in the United States designed to produce qualified advanced technology vehicles or qualified components; and (2) engineering integration performed in the United States of qualifying advanced technology vehicles and qualifying components. Eligible costs of such projects are: (a) Those costs that are reasonably related to the reequipping, expanding, or establishing a manufacturing facility in the United States to produce qualifying advanced technology vehicles or qualifying components; (b) costs of engineering integration performed in the United States for qualifying vehicles or qualifying components. Costs eligible for payment with loan proceeds are costs incurred, but not yet paid by the borrower, after a substantially complete application has been submitted to DOE and costs incurred after the closing of the loan.

The statute defines ''advanced technology vehicle'' as—

[L]ight duty vehicle that meets—

(A) the Bin 5 Tier II emission standard established in regulations issued by the Administrator of the Environmental Protection Agency under section 202(i) of the Clean Air Act (42 U.S.C. 7521(i)), or a lower-numbered Bin emission standard;

(B) any new emission standard in effect for fine particulate matter prescribed by the Administrator under that Act (42 U.S.C. 7401 et seq.); and

(C) at least 125 percent of the average base year combined fuel economy for vehicles with substantially similar attributes.

(42 U.S.C. 17013(a)(1))

As stated above, the statute does not define ''light duty vehicle.'' DOE interprets ''light duty vehicles'' to be vehicles currently subject to the CAFE requirements under EPCA, (i.e., passenger automobiles and light trucks).

The first two provisions of the statutory definition of ''advanced technology vehicle'' ensure that such a vehicle has low emissions. Pursuant to its authority under the Clean Air Act, on February 10, 2000, the EPA published a final rule establishing new Federal emission standards for passenger cars and light trucks (see *65 FR 6698*). Known as the Tier II Program, the emissions standards in EPA's final rule cover light-duty vehicles (i.e., passenger cars and light trucks with a gross vehicle weight rating (GVWR) of 6,000 pounds or less, as well as ''medium-duty passenger vehicles'' (MDPVs)).[7]

The Tier II standards are designed to reduce the emissions most responsible for the ozone and particulate matter impact from these vehicles (e.g., nitrous oxides and non-methane organic gases) and contributing to ambient volatile organic compounds.

The Tier II emission standards are based on a system of emission bins in which light-duty vehicles are certified in one of eight bins; Bin 1 represents the cleanest or lowest emitting vehicles, and Bin 8 represents the highest emitting vehicles of the Tier II bins. The emission standards for a manufacturer's vehicle fleet must comply on average with the Tier II Bin 5 level. Thus, the Tier II Bin 5 emission certification levels are the average of the Tier II emission levels with lower bins (i.e., 4, 3, 2, or 1) representing lower emitting vehicles and higher bins (i.e., 6, 7, or 8) representing vehicles that are more polluting. 72 FR 29102, 29103 (May 24, 2007). Section 136 limits ''advanced technology vehicles'' to those vehicles that, at a minimum, comply with Bin 5 levels at the time an application is submitted to DOE.

The grant and loan programs provide assistance for the production of vehicles and components that demonstrate advanced fuel economy improvements. In order to qualify as an ''advanced technology vehicle'' a vehicle must meet at least 125 percent of the average base year combined fuel economy for vehicles with substantially similar attributes.[8] It should be noted that the at least 25 percent improvement in fuel economy performance necessary for a vehicle to qualify as an advanced technology vehicle is the minimum improvement necessary for eligibility under the section 136 grant and loan programs. As discussed later in this notice, in prioritizing projects to receive either a grant or a loan, DOE will consider the extent to which an advanced technology vehicle exceeds the 125 percent minimum.

For the purpose of demonstrating the at least 25 percent improvement, vehicle fuel economies are compared without consideration of whether the vehicles are dual fueled automobiles under CAFE. A ''dual fueled automobile'' is an automobile that is capable of operating on alternative fuel or a mixture of biodiesel and diesel, and on gasoline or diesel. 49 U.S.C. 32901(a)(9). Dual fueled vehicles are commonly referred to as flexible fuel vehicles.

The CAFE statute specifies special calculations for determining the fuel economy of dual fueled automobiles that give those vehicles higher fuel economy ratings than automobiles that

[5] At this time, no funds have been appropriated for the purpose of making grant awards under section 136(b).

[6] As discussed later in this document, section 136 does not place a restriction on the percent of costs eligible under the direct loan program.

[7] An MDPV is defined as a light truck rated at more than 8,500 lbs GVWR, or that has a vehicle curb weight of more than 6,000 pounds, or that has a basic vehicle frontal area in excess of 45 square feet. MDPV does not include a vehicle that:

Is an ''incomplete truck''; or

Has a seating capacity of more than 12 persons; or

Is designed for more than 9 persons in seating rearward of the driver's seat; or

Is equipped with an open cargo area (for example, a pick-up truck box or bed) of 72.0 inches in interior length or more. A covered box not readily accessible from the passenger compartment will be considered an open cargo area for purposes of this definition.

40 CFR 86–1803–01.

[8] In calculating the percent improvement in average base year combined fuel economy, if the vehicle at issue is an all electric drive, a range extended electric vehicle, or a plug in hybrid vehicle, then the applicant will need to submit information that allows the Department to determine that the vehicle meets the 125% average combined fuel economy test.

are identical except that they are not dual fueled.[9] 49 U.S.C. 32905(b). The incentive provided to dual fueled vehicles was enacted to encourage the production of vehicles that would promote consumer acceptance and ultimately lead to the development of infrastructure to distribute and make alternative fuel available. (See 69 FR 7689, 7691; February 19, 2004.) While DOE supports the development and increased distribution of dual fueled vehicles, we have determined not to consider dual fueled capabilities under the criteria for identifying an advanced technology vehicle. For the purpose of determining whether a vehicle achieves a fuel economy performance of at least 125 percent of the average base year combined fuel economy for vehicles with substantially similar attributes, DOE will consider the fuel economy performance of vehicles as calculated for non-dual fueled vehicles.

Section 136 does not define the term ''base year'' and therefore DOE may exercise its sound policy discretion in defining that term. DOE is defining ''base year'' as MY 2005.

DOE recognizes that the fuel economy standard for light trucks increases in stringency through MY 2010, and that NHTSA has proposed to increase the stringency of both the passenger car and further increase the light truck fuel economy standard beginning MY 2011. See 49 CFR 533.5 and 73 FR 24352, respectively. Given the potential for a vehicle that is the subject of an application to begin being manufactured in a future MY, DOE considered using a future MY for the base year. However, the definition of ''advanced technology vehicle'' requires a fuel economy performance comparison to be in terms of vehicles with ''substantially similar attributes.''

At present, DOE does not have sufficient data on the types of vehicles to be manufactured in future MYs, including the fuel economy performance of vehicles yet to be manufactured. Although manufacturers have product plans for future years, that information is subject to change. DOE considered relying on fuel economy targets established for specific vehicle footprint values (i.e., area calculated by multiplying vehicle width by vehicle length). In the MYs 2008–2010, standards for light trucks, NHTSA assigns a fuel economy target for each light truck based on vehicle footprint. 49 CFR 533.5. There are currently no similar targets established for passenger automobiles.

As a result of the lack of sufficient data for future MYs and the lack of attribute-based fuel economy targets for passenger cars, DOE has decided that the ''base year'' should be a year for which CAFE compliance data are available. To date, NHTSA has not received all of the approved compliance data from EPA for MY 2007.[10] DOE notes that the total fleet fuel economy for MY 2006 is higher than in MY 2005 (25.8 mpg as compared to 25.4 mpg), the industry average for passenger automobile fuel economy is higher in MY 2005 than in MY 2006 (30.3 mpg as compared to 30.1 mpg).[11] However, relying on MY 2006 as a base year would not necessarily result in a more stringent fuel economy comparison for determining whether a particular vehicle is an advanced technology vehicle. Furthermore, MY 2005 CAFE data are fully available and known at the present time, and using MY 2005 would promote efficient and effective administration of the section 136 program. Thus, and consistent with the model year for which Congress established automobile manufacturer eligibility under section 136(e), DOE has interpreted base year for the purpose of defining an ''advanced technology vehicle'' to mean MY 2005.

A determination of whether a vehicle has sufficiently improved fuel economy to qualify as an advanced technology vehicle is further refined by section 136's reference to vehicles with ''substantially similarly attributes.'' To identify those vehicles with substantially similar attributes, DOE first relied on the vehicle classes used for EPA's fuel economy guidelines. EPA, in conjunction with DOE, publishes information on the fuel economy performance of the vehicle fleet for each model year.[12] EPA segments the vehicle fleet by size classes to permit more practicable comparisons of fuel economy performance between vehicles. The size class for cars is based on interior passenger and cargo volumes as described below. The size class for trucks is defined by GVWR, which is the weight of the vehicle and its carrying capacity. For MY 2005, EPA has identified the various classes as follows.

Class	Passenger & cargo volume (cu. ft.)
Cars	
Two-Seaters	Any (cars designed to seat only two adults).
Sedans	
Minicompact	< 85.
Subcompact	85–99.
Compact	100–109.
Mid-Size	110–119.
Large	120 or more.
Station Wagons	
Small	<130.
Mid-Size	130–159.
Large	160 or more.
Class	Gross Vehicle Weight Rating (GVWR)
Trucks	
Pickup Trucks	
Small	< 4,500 pounds.

[9] Through MY 2014, manufacturers may use this ''dual-fuel'' incentive to raise their average fuel economy up to 1.2 miles a gallon higher than it would otherwise be; after MY 2014, Congress has set a schedule by which the dual-fuel incentive diminishes ratably until it is extinguished after MY 2019. 49 U.S.C. 32906(a).

[10] For CAFE compliance purposes the average fuel economy of passenger automobiles and light trucks is determined in accordance with procedures established by EPA. 49 CFR 531.6(a) and 533.6(b), respectively. To date, EPA has not approved the data for Ford's domestic passenger automobile fleet.

[11] Summary of Fuel Economy Performance, NHTSA (March 2008).

[12] *http://www.fueleconomy.gov/feg/info.shtml* (last visited October 30, 2008).

Class	Passenger & cargo volume (cu. ft.)
Standard	4,500–8,500 pounds.
Vans	
Passenger	< 8,500 pounds.
Cargo	< 8,500 pounds.
Minivans	< 8,500 pounds.
Sport Utility Vehicles (SUVs)	< 8,500 pounds.

DOE notes that in MY 2005 not every EPA vehicle class was populated by vehicle models manufactured in that model year (i.e., small pickups and large wagons). If an EPA class did not have a representative MY 2005 model, DOE combined that class with another EPA class in a manner consistent with the grouping of vehicles by ''substantially similar attributes.''

DOE further categorized vehicles by performance. Performance vehicles generally have lower fuel economy ratings than non-performance vehicles in the same EPA class. Also, different fuel economy technologies may be applicable to performance as opposed to non-performance vehicles (i.e., additional aerodynamic improvements may not be available for performance vehicles). In order to distinguish between vehicles that are manufactured to achieve higher performance from other similarly sized non-performance vehicles, DOE evaluated the peak horsepower to curb weight ratio of each vehicle in a size class. DOE plotted the peak horsepower to curb weight ratio for each vehicle by EPA class. Generally, if there was at least a doubling of the peak horsepower to curb weight ratio along the plotted line, as compared to the lowest plotted value, DOE then looked at the plotted data to see if there was a reasonably identifiable point beyond the doubling that divided the vehicles, i.e., a break point. For those classes in which DOE was able to identify a break point, DOE created an additional ''performance'' class. DOE identified a point in several of the EPA classes at which there was a substantial increase in the ratio. In those instances in which there was a marked increase, the more powerful vehicles were placed into a ''performance class.'' This additional analysis resulted in a total of 17 classes.

Class of vehicles with substantially similar attributes	Example of MY 2005 vehicles
Two-seater	Mazda MX–5 Miata, Chrysler Crossfire Roadster, Porsche Boxter.
Two Seater Performance	GMC Corvette, Mercedes SL65 AMG, Chrysler Viper Coupe.
Minicompact sedan	Mini Cooper, Volkswagen Beetle Convertible, Mitsubishi Eclipse Spyder.
Minicompact sedan Performance	Porsche 911, Ford Jaguar XKR Convertible, Mercedes CLK55 AMG.
Subcompact sedan	GMC Aveo, Toyota Celica, Honda Acura.
Subcompact performance sedan	Mercedes CLK500, BMW M3.
Compact sedan	Volkswagen Jetta, Toyota Corolla, Ford Focus, Chrysler Sebring convertible.
Compact performance sedan	Mercedes CL 55 AMG, Bentley Continental GT.
Mid-size sedan	Mercury Sable, Chevrolet Malibu, Honda Accord, GM Monte Carlo, Hyundai Sonata, Toyota Camry, Nissan Altima.
Mid-size performance sedan	Ford Jaguar S–Type, Mercedes E55 AMG, Nissan Infiniti G35.
Large sedan	Mercedes S C lass, Cadillac Deville, Kia Amanti, Dodge 300 Base, Ford Five Hundred, General Motors Impala.
Small wagon	Toyota Corolla Matrix, GMC Vibe, Chrysler PT Cruiser, Toyota Scion.
Mid-size and large wagons	Volkswagen Passat Wagon, Ford Taurus wagon, Mercedes E320, GM Saab 9–5 Wagon.
Small and standard pickup	Ford F150, GM Silverado, Nissan Frontier, Dodge Dakota, Toyota Tundra, GM Sierra.
Minivan	Dodge Caravan, Chrysler Town & Country, Toyota Sienna, GMC Montana, Nissan Quest, Honda Odyssey, Ford Monterey Wagon.
Cargo van	Chevrolet Astro, Ford E150.
Sport Utility Vehicle	Jeep Wrangler, Ford Escape, Chevrolet Blazer, Range Rover, Mercedes M-class, GM Equinox, Toyota Sequoia, GMC Envoy.

In order to determine the average combined fuel economy for each class, DOE will calculate the harmonic production weighted average for each class. As previously stated, DOE relied on the MY 2005 CAFE compliance data that are available, and assumed each vehicle was a non-dual fueled vehicle.

Vehicle class	Power [1]/ weight [2]	2005 Fuel economy average [3]	2005 mpg × 125%
Two-Seater	< 0.121	25.3	31.6
Two-Seater Performance	≥ 0.121	22.2	27.8
Minicompact Sedan	< 0.088	29.3	36.7
Minicompact Performance Sedan	≥ 0.088	22.4	28.0
Subompact Sedan	< 0.082	29.6	37.0
Subcompact Performance Sedan	≥ 0.082	22.8	28.5
Compact Sedan	< 0.073	33.8	42.2
Compact Performance Sedan	≥ 0.073	23.6	29.5
Mid-Size Sedan	< 0.085	29.4	36.7
Mid-Size Performance Sedan	≥ 0.085	23.1	28.9

Vehicle class	Power [1]/ weight [2]	2005 Fuel economy average [3]	2005 mpg × 125%
Large Sedan	n/a	26.2	32.7
Small Wagon	n/a	32.7	40.8
Mid-Size and Large Wagons	n/a	26.7	33.4
Small and Standard Pickup	n/a	19.7	24.6
Minivan	n/a	24.3	30.4
Passenger Van	n/a	19.0	23.8
Cargo Van	n/a	24.2	30.2
Sport Utility Vehicle	n/a	21.8	27.2

[1] Peak horsepower (hp).
[2] Curb weight (lbs).
[3] Harmonic production weighted average of combined fuel economy.

A project eligible for a grant or loan under section 136 may include a project for ''reequipping, expanding, or establishing a manufacturing facility in the United States to produce'' a ''qualifying component.'' (42 U.S.C. 17031(b)(1)) Section 136 defines ''qualifying component'' as a component that

> [T]he Secretary determines to be—
> (A) designed for advanced technology vehicles; and
> (B) installed for the purpose of meeting the performance requirements of advanced technology vehicles.

(42 U.S.C. 17013(a)(4))

Although a component needs to be designed for an advanced technology vehicle and installed to assist meeting performance requirements of an advanced technology vehicle, DOE does not interpret the statutory definition to mean that the use of these components in either other conventional vehicles or in aftermarket sales is precluded. In making a determination on component eligibility, the Secretary will consider factors such as the overall impact of the component and extent to which the component contributes to the efficiency of advanced technology vehicles.

Eligible costs for facilities that manufacture qualified components may include the costs of ''engineering integration performed in the United States of qualifying vehicles and qualifying components.'' (42 U.S.C. 17013(b)(2)) ''Engineering integration'' is defined to include—

> [T]he cost of engineering tasks relating to—
> (A) incorporating qualifying components into the design of advanced technology vehicles; and
> (B) designing tooling and equipment and developing manufacturing processes and material suppliers for production facilities that produce qualifying components or advanced technology vehicles.

(49 U.S.C. 17013(a)(3))

In both the specification of eligible activities and the definition of ''engineering integration,'' eligible engineering integration costs relate to those costs associated with advanced technology vehicles and qualifying components. Subsection (b) of section 136 states that facility funding awards are for the cost of engineering integration performed in the United States for qualifying vehicles and qualifying components. (42 U.S.C. 17013(b)(2)) ''Engineering integration'' is statutorily defined to include the cost of incorporating qualifying components into the design of an advanced technology vehicle and the costs of design and development for production facilities producing qualifying components or advanced technology vehicles. Engineering costs not associated with the production of an advanced technology vehicle or the production of a qualifying component, are not eligible costs under section 136.

D. Terms for Direct Loans

Section 136 prescribes certain specific terms for loan documents. First, the statute establishes that the loans will have an interest rate that, ''as of the date on which the loan is made, is equal to the cost of funds to the Department of the Treasury for obligations of comparable maturity[.]'' In determining the date upon which the interest rate will be calculated, the Department of the Treasury will set the loan rate at the time the loan funds are disbursed. Additionally, the statute prescribes that the loans shall have a term ''equal to the lesser of—(i) the projected life, in years, of the eligible project to be carried out using funds from the loan, as determined by the Secretary; and (ii) 25 years[.]''

The statute also states that loans may be subject to a deferral in repayment for ''not more than 5 years after the date on which the eligible project carried out using funds from the loan first begins operations, as determined by the Secretary[.]'' Section 136 is silent as to whether a deferral is available for interest on the loan. In today's interim final rule, the Department interprets the deferral of repayment option to apply to only loan principal, not interest. Allowing a deferral of interest would have the effect of increasing the principal amount of the loan, perhaps beyond the authority provided by Congress for this program. Moreover, the statute allows only for deferral of ''repayment'' of a loan. The principal amount of a loan is the amount that is actually being ''repaid'' to the Government. Finally, the statute requires that all loans be made by the Federal Financing Bank.

In addition to the minimum terms prescribed in section 136, today's interim final rule sets forth other parameters for loan terms intended to protect the significant taxpayer costs for this program. Accordingly, the rule states that the Secretary must have a first lien or security interest in all property acquired with loan funds. This requirement may be waived only by the Secretary on a non-delegable basis. Additionally, DOE must also have a lien on any other property of the applicant pledged to secure the loan.

E. Application Process for Direct Loan Program

Section 136 states that applicants for direct loans shall submit applications ''at such time, in such manner, and containing such information as the Secretary may require[.]'' To further the statutory purpose of providing funding to assist in the development and production of advanced technology vehicles and qualifying components, applications for the first tranche of direct loans will be due on the date the interim final rule becomes effective. The deadline for loan applications for subsequent tranches of loans will be every 90 days thereafter as funds and available loan authority permit. The Department will evaluate and make decisions on a tranche of loan applications before proceeding to evaluate and make decisions on a subsequent tranche of loan applications. Application requirements are set forth in section 611.101. These application

materials are intended to provide adequate information for the Department to comply with the requirements and goals of section 136 and other applicable legal and regulatory requirements. One such requirement, written assurance that all laborers and mechanics are paid prevailing wages, explicitly appears in section 136(d)(2) and appears in today's interim final rule. Other requirements in section 136 relate to Secretarial determinations of applicant eligibility such as: (i) Financial viability absent receipt of additional Federal funding associated with the proposed project and (ii) the efficient and effective expenditure of loan proceeds. Today's interim final rule specifies the information to be submitted by an applicant in order for the Secretary to be able to make such determinations.

F. Credit Subsidy Cost for Direct Loans

To date, Congress has appropriated $7,500,000,000 to cover the subsidy cost of the direct loans issued under section 136, and provided an overall cap of $25,000,000,000 on the principal amount of the loans that may be issued. Under the Federal Credit Reform Act of 1990, the subsidy cost reflects ''the estimated long-term cost to the Government of the direct loan, calculated on a net present value basis, excluding administrative costs and any incidental effects on governmental receipts or outlays.'' 2 U.S.C. 661a(5)(A). This amount will be unique for each loan issued under section 136, and is dependent on the particular circumstances of the borrower and the project for which the loan will be issued. While Congress has appropriated funds at approximately a 30 percent subsidy rate, the subsidy cost for individual borrowers and projects may be valued at more or less than 30 percent. If the subsidy costs are estimated to be higher than 30 percent the Department will only be able to issue loans which may be covered by the actual amount appropriated for use as the subsidy, an amount which will not reach the $25,000,000,000 cap. Thus, while there is a limit on the total amount of loans the Department is able to make, the value of the loans the Department is able to make with the credit subsidy amount appropriated may be less than $25,000,000,000.

G. Project Costs

Section 136 states that awards under the grant program for eligible projects shall pay ''not more than 30 percent'' of project cost. On the other hand, section 136 does not impose a maximum percentage of funding associated with a particular project for the direct loan program. In accordance with Federal credit policies under OMB Circular A–129, the Department will adhere to requirements for a significant borrower stake. Under the interim final rule, the Federal loan may only constitute up to 80% of a project's cost. Section 611.102 sets forth the types of costs the Department will consider to be eligible project costs—i.e., costs for which grant or loan proceeds may be expended. Eligible costs are: (a) Those costs that are reasonably related to the reequipping, expanding, or establishing a manufacturing facility in the United States to produce qualifying advanced technology vehicles or qualifying components; (b) costs of engineering integration performed in the United States for qualifying vehicles or qualifying components. Costs eligible for payment with loan proceeds are costs incurred, but not yet paid by the borrower, after a substantially complete application has been submitted to DOE and costs incurred after the closing of the loan. In determining the overall total cost of an Eligible Project, DOE and the applicant may include significant costs already incurred and capitalized by the applicant in accordance with Generally Accepted Accounting Principles and these costs may be considered by DOE in determining the Borrower's contribution to total project costs.

H. Assessment of Fees for Direct Loans

Section 136(f) states that administrative costs ''shall be no more than $100,000 or 10 basis points of the loan.'' The Department interprets this subsection as authorizing DOE to charge borrowers an administrative fee, which shall be deposited into the U.S. Treasury, and as providing DOE with the flexibility to choose either monetary option set forth in the statute. DOE has decided that administrative costs for a particular loan will be 10 basis points of the loan to be paid by the borrower on the closing date of the loan. No application fee will be charged, and therefore applicants that do not receive a loan will pay no administrative fee. The Department bases its decision on the need for fairness among applicants and the belief that administrative costs for a loan will be in excess of 10 basis points. By including a fee provision in section 136, Congress demonstrated an intent that applicants should pay a fee in connection with a loan. By selecting 10 basis points as the fee for all loans, the Department assures that applicants for smaller loans will pay smaller fees.

I. Assessment of Applications and Priorities

All applications received will be reviewed to determine whether the applicant is eligible and that the application contains all information required of an applicant by section 136, this interim final rule and other applicable law. Applications that are determined to be eligible and substantially complete will undergo a substantive review by DOE based upon certain evaluation factors. These factors include, but are not limited to, the technical merit of the proposed advanced technology vehicles or qualifying components, with greater weight given for improved vehicle fuel economy above the minimum required for an advanced technology vehicle, potential contributions to improved fuel economy of the U.S. light-duty vehicle fleet, promotion of the use of advanced fuel (e.g., E85, ultra-low sulfur diesel), and potential reductions in petroleum use by the U.S. light-duty fleet. DOE will also assess the adequacy of the proposed provisions to protect the Government, including offers of participation in project gains, sufficiency of Security, the priority of the lien position in the Security, and the percentage of the project to be financed with the loan.

III. Application Submission

Section 611.101 of this interim final rule sets forth the information DOE will need an applicant to submit in order to make the determinations required in section 136 and this interim final rule for issuance of a loan or award. Applicants may submit loan requests for multiple eligible projects in a single application provided that the application provides a way to segregate each proposed eligible project in such a way that permits DOE to evaluate each project in the application. Applications for the first tranche of loans may be submitted or hand delivered to the Postal Mail address listed in **ADDRESSES**. DOE will consider and evaluate substantially complete applications as and when they are submitted during the first tranche period, which will close December 31, 2008. DOE may make decisions on such applications and close loans with respect to such applications at any time. After December 31, 2008, subsequent tranche periods will close on the last day of each calendar year quarter (i.e., March 31, 2009; June 30, 2009, etc.) For applications submitted during those subsequent periods, no final decisions will be made with respect to such

applications until after the close of the particular tranche period.

IV. Regulatory Review

A. Executive Order 12866

Today's interim final rule has been determined to be an economically significant regulatory action under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB).

B. National Environmental Policy Act

Through the issuance of this rule, DOE is making no decision relative to the approval of a loan or grant for a particular project. DOE has, therefore, determined that publication of this rule is covered under the Categorical Exclusion found at paragraph A.6 of Appendix A to Subpart D, 10 CFR Part 1021, which applies to the establishment of procedural rulemakings. Accordingly, neither an environmental assessment nor an environmental impact statement is required at this time. However, appropriate NEPA project review will be conducted in connection with a section 136 loan or grant.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://www.gc.doe.gov*.

Because a notice of proposed rulemaking is not required pursuant to 5 U.S.C. 553, EISA section 136, as amended, or any other law, prior to issuance of this interim final rule, the analytical requirements of the Regulatory Flexibility Act are inapplicable. As such, DOE is not obliged to prepare a regulatory flexibility analysis for this rulemaking.

D. Paperwork Reduction Act

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been submitted to OMB with a request for emergency processing. DOE will publish a notice of approval once received from OMB.

Public reporting burden for this collection of information is estimated to average 256.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate, or any other aspect of the data collection, including suggestions for reducing the burden, to DOE (see Postal Mail in **ADDRESSES**) or to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

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.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Act) (2 U.S.C. 1531 *et seq.*) requires each federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any federal mandate in an agency rule that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The Act also requires a federal agency to develop an effective process to permit timely input by elected officials of state, tribal, or local governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity to provide timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments.

The term ''federal mandate'' is defined in the Act to mean a federal intergovernmental mandate or a federal private sector mandate (2 U.S.C. 658(6)). Although the rule will impose certain requirements on non-federal governmental and private sector applicants for loans, the Act's definitions of the terms ''federal intergovernmental mandate'' and ''federal private sector mandate'' exclude, among other things, any provision in legislation, statute, or regulation that is a condition of federal assistance or a duty arising from participation in a voluntary program (2 U.S.C. 658(5) and (7), respectively). Today's interim final rule establishes requirements that persons voluntarily seeking loans for projects that would use certain advanced vehicle technologies must satisfy as a condition of a federal loan. Thus, the interim final rule falls under the exceptions in the definitions of ''federal intergovernmental mandate'' and ''federal private sector mandate'' for requirements that are a condition of federal assistance or a duty arising from participation in a voluntary program. Accordingly, the Unfunded Mandates Reform Act of 1995 does not apply to this rulemaking.

F. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

G. Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this interim final rule and has determined that it would not preempt State law and 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, no further action is required by Executive Order 13132.

H. Executive Order 12988

With respect to the review of existing regulations and the promulgation of

new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

I. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Today's regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

K. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of today's interim final rule. The report will state that it has been determined that the interim final rule is a ''major rule'' as defined by 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 808(2), DOE finds good cause that the effective date of this major rule need not be delayed because notice and public procedure thereon are unnecessary, impracticable, and contrary to the public interest. In the Continuing Resolution, 2009, Congress amended section 136 of EISA to require DOE to act with extreme expedition in the establishment and implementation of the Advanced Technology Vehicle Manufacturing Incentive Program. Specifically, Congress mandated that the Secretary issue an interim final rule—a rule that is issued and becomes effective without prior public notice and comment. Furthermore, Congress mandated that this interim final rule be promulgated no later than 60 days after enactment of the Continuing Resolution 2009. In addition, the Department is cognizant of the current extraordinary and adverse credit market conditions, and believes it would be contrary to the public interest to delay the effective date of regulations implementing a program that may help respond to those conditions. Thus, it would be inconsistent with that Congressional mandate, and thereby unnecessary, impracticable and contrary to the public interest, for the effective date of this interim final rule to be delayed beyond the date of its publication. For the reasons stated above, DOE also finds good cause, pursuant to 5 U.S.C. 553(d)(3), to waive the 30-delay in effective date required by the rulemakings provisions of the Administrative Procedure Act.

L. Approval by the Office of the Secretary of Energy

The Secretary of Energy has approved the issuance of this interim final rule.

List of Subjects in 10 CFR Part 611

Administrative practice and procedure, Energy, Loan programs, and Reporting and recordkeeping requirements.

Issued in Washington, DC, on November 5, 2008.

Owen Barwell,

Deputy Chief Financial Officer.

■ For the reasons stated in the Preamble, chapter II of title 10 of the Code of Federal Regulations is amended by adding a new part 611 as set forth below.

PART 611—ADVANCED TECHNOLOGY VEHICLES MANUFACTURER ASSISTANCE PROGRAM

Subpart A—General

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§ 611.2 Definitions.
§ 611.3 Advanced technology vehicle.

Subpart B—Direct Loan Program

§ 611.100 Eligible applicant.
§ 611.101 Application.
§ 611.102 Eligible project costs.
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§ 611.105 Agreement.
§ 611.106 Environmental requirements.
§ 611.107 Loan terms.
§ 611.108 Perfection of liens and preservation of collateral.
§ 611.109 Audit and access to records.
§ 611.110 Assignment or transfer of loans.
§ 611.111 Default, demand, payment, and collateral liquidation.
§ 611.112 Termination of obligations.

Subpart C—Facility Funding Awards

§ 611.200 Purpose and scope.
§ 611.201 Applicability.
§ 611.202 Advanced Technology Vehicle Manufacturing Facility Award Program.
§ 611.203 Eligibility.
§ 611.204 Awards.
§ 611.205 Period of award availability.
§ 611.206 Existing facilities.
§ 611.207 Small automobile and component manufacturers.
§ 611.208 [Reserved].
§ 611.209 [Reserved].

Authority: Pub. L. 110–140 (42 U.S.C. 17013), Pub. L. 110–329.

Subpart A—General

§ 611.1 Purpose.

This part is issued by the Department of Energy (DOE) pursuant to section 136

of the Energy Independence and Security Act of 2007, Public Law 110–140, as amended by section 129 of Public Law 110–329. Specifically, section 136(e) directs DOE to promulgate an interim final rule establishing regulations that specify eligibility criteria and that contain other provisions that the Secretary deems necessary to administer this section and any loans made by the Secretary pursuant to this section.

§ 611.2 Definitions.

The definitions contained in this section apply to provisions contained in both Subpart A and Subpart B.

Adjusted average fuel economy means a harmonic production weighted average of the combined fuel economy of all vehicles in a fleet, which were subject to CAFE.

Advanced technology vehicle means a passenger automobile or light truck that meets—

(1) The Bin 5 Tier II emission standard established in regulations issued by the Administrator of the Environmental Protection Agency under section 202(i) of the Clean Air Act (42 U.S.C. 7521(i)), as of the date of application, or a lower-numbered Bin emission standard;

(2) Any new emission standard in effect for fine particulate matter prescribed by the Administrator under that Act (42 U.S.C. 7401 *et seq.*), as of the date of application; and

(3) At least 125 percent of the harmonic production weighted average combined fuel economy, for vehicles with substantially similar attributes in model year 2005.

Agreement means the contractual loan arrangement between DOE and a Borrower for a loan made by and through the Federal Financing Bank with the full faith and credit of the United States government on the principal and interest.

Applicant means a party that submits a substantially complete application pursuant to this Part.

Application means the compilation of the materials required by this Part to be submitted to DOE by an Applicant. One Application can include requests for one or more loans and one or more projects. However, an Application covering more than one project must contain complete and separable information with respect to each project.

Automobile is used as that term is defined in 49 CFR Part 523.

Borrower means an Applicant that receives a loan under this Program.

CAFE means the Corporate Average Fuel Economy program of the Energy Policy and Conservation Act, 49 U.S.C. 32901 *et seq.*

Combined fuel economy means the combined city/highway miles per gallon values, as are reported in accordance with section 32904 of title 49, United States Code. If CAFE compliance data is not available, the combined average fuel economy of a vehicle must be demonstrated through the use of a peer-reviewed model.

DOE or *Department* means the United States Department of Energy.

Eligible Facility means a manufacturing facility in the United States that produces qualifying advanced technology vehicles, or qualifying components.

Eligible Project means:

(1) Reequipping, expanding, or establishing a manufacturing facility in the United States to produce qualifying advanced technology vehicles, or qualifying components; or

(2) Engineering integration performed in the United States for qualifying advanced technology vehicles and qualifying components.

Engineering integration costs are the costs of engineering tasks relating to—

(1) Incorporating qualifying components into the design of advanced technology vehicles; and

(2) Designing tooling and equipment and developing manufacturing processes and material suppliers for production facilities that produce qualifying components or advanced technology vehicles.

Equivalent vehicle means a light-duty vehicle of the same vehicle classification as specified in 10 CFR Part 523.

Financially viable means a reasonable prospect that the Applicant will be able to make payments of principal and interest on the loan as and when such payments become due under the terms of the loan documents, and that the applicant has a net present value that is positive, taking all costs, existing and future, into account.

Grantee means an entity awarded a grant made pursuant to section 136 and this Part.

Light-duty vehicle means passenger automobiles and light trucks.

Light truck is used as that term is defined in 49 CFR Part 523.

Loan Documents mean the Agreement and all other instruments, and all documentation among DOE, the borrower, and the Federal Financing Bank evidencing the making, disbursing, securing, collecting, or otherwise administering the loan [references to loan documents also include comparable agreements, instruments, and documentation for other financial obligations for which a loan is requested or issued].

Model year is defined as that term is defined in 49 U.S.C. 32901.

Passenger automobile is used as that term is defined in 49 CFR Part 523.

Qualifying components means components that the DOE determines are

(1) Designed for advanced technology vehicles; and

(2) Installed for the purpose of meeting the performance requirements of advanced technology vehicles.

Secretary means the United States Secretary of Energy.

Security means all property, real or personal, tangible or intangible, required by the provisions of the Loan Documents to secure repayment of any indebtedness of the Borrower under the Loan Documents.

§ 611.3 Advanced technology vehicle.

In order to demonstrate that a vehicle is an ''advanced technology vehicle'', an automobile manufacturer must provide the following:

(a) Emissions certification. An automobile manufacturer must written certify that the vehicle meets, or will meet, the emissions requirements specified in the definition of ''advanced technology vehicle''; and

(b) Demonstration of fuel economy performance. An automobile manufacturer must demonstrate that the vehicle has a combined average fuel economy of at least 125 percent of the average combined fuel economy for vehicles with substantially similar attributes for model year 2005.

(1) A combined average fuel economy calculation required under this paragraph for a vehicle that is a dual fueled automobile for the purpose of CAFE is calculated as if the vehicle were not a dual fueled automobile.

(2) The average combined fuel economy for vehicles with substantially similar attributes is a harmonic production weighted average of the combined average fuel economy of all vehicles with substantially similar attributes in model year 2005, as published by DOE.

(3) In the case of an electric drive vehicle with the ability to recharge from an off-board source, an automobile manufacturer must provide DOE with a test procedure and sufficient data to demonstrate that the vehicle meets or exceeds the applicable average combined fuel economy of vehicles with substantially similar attributes.

Subpart B—Direct Loan Program

§ 611.100 Eligible applicant.

(a) In order to be eligible to receive a loan under this part, an applicant

(1) Must be either—

(i) An automobile manufacturer that can demonstrate an improved fuel economy as specified in paragraph (b) of this section, or

(ii) A manufacturer of a qualifying component; and

(2) Must be financially viable without receipt of additional Federal funding associated with the proposed eligible project.

(b) Improved fuel economy. (1) If the applicant is an automobile manufacturer that manufactured in model year 2005, vehicles subject to the CAFE requirements, the applicant must demonstrate that its adjusted average fuel economy for its light-duty vehicle fleet produced in the most recent year for which final CAFE compliance data is available, at the time of application, is greater than or equal to the adjusted average fuel economy of the applicant's fleet for MY 2005, based on the MY 2005 final CAFE compliance data.

(2) If the applicant is an automobile manufacturer that did not manufacture in model year 2005, vehicles subject to the CAFE requirements, the applicant must demonstrate that the projected combined fuel economy for the relevant the advanced technology vehicle that is the subject of the application is greater than or equal to the industry adjusted average fuel economy for model year 2005 of equivalent vehicles, based on final CAFE compliance data.

(3) The CAFE values under this paragraph are to be calculated using the CAFE procedures applicable to the model year being evaluated.

(4) An applicant must provide fuel economy data, at the model level, relied upon to make the demonstration required by this section.

(5) An applicant that is a manufacturer of a qualifying component under paragraph (a)(1)(ii) of this section does not need to make a showing of improved fuel economy under this paragraph.

(c) In determining under paragraph (a)(2) of this section whether an applicant is financially viable, the Department will consider a number of factors, including, but not limited to:

(1) The applicant's debt-to-equity ratio as of the date of the loan application;

(2) The applicant's earnings before interest, taxes, depreciation, and amortization (EBITDA) for the applicant's most recent fiscal year prior to the date of the loan application;

(3) The applicant's debt to EBITDA ratio as of the date of the loan application;

(4) The applicant's interest coverage ratio (calculated as EBITDA divided by interest expenses) for the applicant's most recent fiscal year prior to the date of the loan application;

(5) The applicant's fixed charge coverage ratio (calculated as EBITDA plus fixed charges divided by fixed charges plus interest expenses) for the applicant's most recent fiscal year prior to the date of the loan application;

(6) The applicant's liquidity as of the date of the loan application;

(7) Statements from applicant's lenders that the applicant is current with all payments due under loans made by those lenders at the time of the loan application; and

(8) Financial projections demonstrating the applicant's solvency through the period of time that the loan is outstanding.

(d). For purposes of making a determination under paragraph (a)(2) of this section, additional Federal funding includes any loan, grant, guarantee, insurance, payment, rebate, subsidy, credit, tax benefit, or any other form of direct or indirect assistance from the Federal government, or any agency or instrumentality thereof, other than the proceeds of a loan approved under this Part, that is, or is expected to be made available with respect to, the project for which the loan is sought under this Part.

§ 611.101 Application.

An application must include, at a minimum, the following information and materials:

(a) A certification by the applicant that it meets each of the requirements of the program as set forth in statute, the regulations in this part, and any supplemental requirements issued by DOE;

(b) A description of the nature and scope of the proposed project for which a loan or award is sought under this part, including key milestones and location of the project;

(c) A detailed explanation of how the proposed project qualifies under applicable law to receive a loan or award under this part, including vehicle simulations using industry standard model (need to add name and location of this open source model) to show projected fuel economy;

(d) A detailed estimate of the total project costs together with a description of the methodology and assumptions used to produce that estimate;

(e) A detailed description of the overall financial plan for the proposed project, including all sources and uses of funding, equity, and debt, and the liability of parties associated with the project;

(f) Applicant's business plan on which the project is based and applicant's financial model presenting project *pro forma* statements for the proposed term of the obligations including income statements, balance sheets, and cash flows. All such information and data must include assumptions made in their preparation and the range of revenue, operating cost, and credit assumptions considered;

(g) An analysis of projected market use for any product (vehicle or component) to be produced by or through the project, including relevant data and assumptions justifying the analysis, and copies of any contractual agreements for the sale of these products or assurance of the revenues to be generated from sale of these products;

(h) Financial statements for the past three years, or less if the applicant has been in operation less than three years, that have been audited by an independent certified public accountant, including all associated notes, as well as interim financial statements and notes for the current fiscal year, of the applicant and parties providing the applicant's financial backing, together with business and financial interests of controlling or commonly controlled organizations or persons, including parent, subsidiary and other affiliated corporations or partners of the applicant;

(i) A list showing the status of and estimated completion date of applicant's required project-related applications or approvals for Federal, state, and local permits and authorizations to site, construct, and operate the project, a period of 5 years preceding the submission of an application under this Part;

(j) Information sufficient to enable DOE to comply with the National Environmental Policy Act of 1969, as required by § 611.106 of this part;

(k) A listing and description of assets associated, or to be associated, with the project and any other asset that will serve as collateral for the Loan, including appropriate data as to the value of the assets and the useful life of any physical assets. With respect to real property assets listed, an appraisal that is consistent with the ''Uniform Standards of Professional Appraisal Practice,'' promulgated by the Appraisal Standards Board of the Appraisal Foundation, and performed by licensed or certified appraisers, is required;

(l) An analysis demonstrating that, at the time of the application, the applicant is financially viable without

receipt of additional Federal funding associated with the proposed project, and that there is a reasonable prospect that the Applicant will be able to make payments of principal and interest on the loan as and when such payments become due under the terms of the loan documents, and that the applicant has a net present value which is positive, taking all costs, existing and future, into account. This information must include, from publicly traded companies, relevant filings with the Securities and Exchange Commission;

(m) Written assurance that all laborers and mechanics employed by contractors or subcontractors during construction, alteration, or repair that is financed, in whole or in part, by a loan under this Part shall be paid wages at rates not less than those prevailing on similar construction in the locality, as determined by the Secretary of Labor in accordance with 40 U.S.C. sections 3141–3144, 3146, and 3147;

(n) Completed Form SF–LLL, as required by 10 CFR Part 601; and

(o) Other information, as determined necessary by DOE.

§ 611.102 Eligible project costs.

(a) Eligible costs are:

(1) Those costs that are reasonably related to the reequipping, expanding, or establishing a manufacturing facility in the United States to produce qualifying advanced technology vehicles or qualifying components;

(2) Costs of engineering integration performed in the United States for qualifying vehicles or qualifying components;

(3) Costs for payment with loan proceeds that are incurred, but not yet paid by the borrower, after a substantially complete application has been submitted to DOE; and

(4) Costs incurred after closing of the loan.

(b) In determining the overall total cost of an Eligible Project, DOE and the applicant may include significant costs already incurred and capitalized by the applicant in accordance with Generally Accepted Accounting Principles and these costs may be considered by DOE in determining the Borrower's contribution to total project costs.

§ 611.103 Application evaluation.

(a) *Eligibility screening.* Applications will be reviewed to determine whether the applicant is eligible, the information required under § 611.101 is complete, and the proposed loan complies with applicable statutes and regulations. DOE can at any time reject an application, in whole or in part, that does not meet these requirements.

(b) *Evaluation criteria.* Applications that are determined to be eligible pursuant to paragraph (a) of this section shall be subject to a substantive review by DOE based upon factors that include, but are not limited to, the following:

(1) The technical merit of the proposed advanced technology vehicles or qualifying components, with greater weight given for factors including, but not limited to:

(i) Improved vehicle fuel economy above that required for an advanced technology vehicle;

(ii) Potential contributions to improved fuel economy of the U.S. light-duty vehicle fleet;

(iii) Likely reductions in petroleum use by the U.S. light-duty fleet; and

(iv) Promotion of use of advanced fuel (e.g., E85, ultra-low sulfur diesel).

(2) Technical Program Factors such as economic development and diversity in technology, company, risk, and geographic location.

(3) The adequacy of the proposed provisions to protect the Government, including sufficiency of Security, the priority of the lien position in the Security, and the percentage of the project to be financed with the loan.

(4) In making loans to those manufacturers that have existing facilities, priority will be given to those facilities that are oldest or have been in existence for at least 20 years even if such facilities are idle at the time of application.

§ 611.104 [Reserved]

§ 611.105 Agreement.

(a) Only an Agreement executed by a duly authorized DOE Contracting Officer can contractually obligate the government to make a loan made by and through the Federal Financing Bank with the full faith and credit of the United States government on the principal and interest.

(b) DOE is not bound by oral representations made during the Application stage, or during any negotiation process.

(c) No funds obtained from the Federal Government, or from a loan or other instrument guaranteed by the Federal Government, may be used to pay administrative fees, or other fees charged by or paid to DOE relating to the section 136 loan program.

(d) Prior to the execution by DOE of an Agreement, DOE must ensure that the following requirements and conditions, which must be specified in the Agreement, are satisfied:

(1) The Borrower is a Eligible Applicant as defined in this Part;

(2) The Agreement is for an Eligible Project as defined in this Part;

(3) The principal amount of the loan is limited to no more than 80 percent of reasonably anticipated total Project Costs;

(4) Loan funds will be disbursed only to meet immediate cash disbursement needs of the Borrower and not for investment purposes, and any investment earnings obtained in excess of accrued interest expense will be returned to United States Government; and

(5) Such documents, representations, warrants and covenants as DOE may require.

§ 611.106 Environmental requirements.

(a)(1) *In general.* Environmental review of the proposed projects under this part will be conducted in accordance with applicable statutes, regulations, and Executive Orders.

(2) The applicant must submit a comprehensive environmental report. The comprehensive environmental report shall consist of the specific reports and related material set forth in paragraphs (d) through (f) of this section.

(3) The regulations of the Council on Environmental Quality implementing NEPA require DOE to provide public notice of the availability of project specific environmental documents such as environmental impact statements, environmental assessments, findings of no significant impact, records of decision etc., to the affected public. See 40 CFR 1506.6(b). The comprehensive environmental report will provide substantial basis for any required environmental impact statement or environmental assessment and findings of no significant impact, pursuant to the procedures set forth in 10 CFR 1021.215. DOE may also make a determination as to whether a categorical exclusion is available with regard to an Application.

(b) The detail of each specific report must be commensurate with the complexity of the proposal and its potential for environmental impact. Each topic in each specific report shall be addressed or its omission justified, unless the specific report description indicates that the data is not required for that type of project. If material required for one specific report is provided in another specific report or in another exhibit, it may be incorporated by reference. If any specific report topic is required for a particular project but is not provided at the time the application is filed, the comprehensive environmental report shall explain why it is missing and when the applicant anticipates it will be filed.

(c) As appropriate, each specific report shall:

(1) Address conditions or resources that might be directly or indirectly affected by the project;

(2) Identify significant environmental effects expected to occur as a result of the project;

(3) Identify the effects of construction, operation (including maintenance and malfunctions), and termination of the project, as well as cumulative effects resulting from existing or reasonably foreseeable projects;

(4) Identify measures proposed to enhance the environment or to avoid, mitigate, or compensate for adverse effects of the project; and

(5) Provide a list of publications, reports, and other literature or communications that were cited or relied upon to prepare each report.

(d) Specific Report 1—Project impact and description. This report must describe the environmental impacts of the project, facilities associated with the project, special construction and operation procedures, construction timetables, future plans for related construction, compliance with regulations and codes, and permits that must be obtained.

(e) Specific Report 2—Socioeconomics. This report must identify and quantify the impacts of constructing and operating the proposed project on factors affecting towns and counties in the vicinity of the project. The report must:

(1) Describe the socioeconomic impact area;

(2) Evaluate the impact of any substantial immigration of people on governmental facilities and services and plans to reduce the impact on the local infrastructure;

(3) Describe on-site manpower requirements and payroll during construction and operation, including the number of construction personnel who currently reside within the impact area, would commute daily to the site from outside the impact area, or would relocate temporarily within the impact area;

(4) Determine whether existing housing within the impact area is sufficient to meet the needs of the additional population;

(5) Describe the number and types of residences and businesses that would be displaced by the project, procedures to be used to acquire these properties, and types and amounts of relocation assistance payments; and

(6) Conduct a fiscal impact analysis evaluating incremental local government expenditures in relation to incremental local government revenues that would result from construction of the project. Incremental expenditures include, but are not limited to, school operating costs, road maintenance and repair, public safety, and public utility costs.

(f) Specific Report 3—Alternatives. This report must describe alternatives to the project and compare the environmental impacts of such alternatives to those of the proposal. The discussion must demonstrate how environmental benefits and costs were weighed against economic benefits and costs, and technological and procedural constraints. The potential for each alternative to meet project deadlines and the environmental consequences of each alternative shall be discussed. The report must discuss the ''no action'' alternative and the potential for accomplishing the proposed objectives through the use of other means. The report must provide an analysis of the relative environmental benefits and costs for each alternative.

§ 611.107 Loan terms.

(a) All loans provided under this part shall be due and payable in full at the earlier of:

(1) the projected life, in years, of the Eligible facility that is built or installed as a result of the Eligible Project carried out using funds from the loan, as determined by the Secretary; or

(2) Twenty-five (25) years after the date the loan is closed.

(b) Loans provided under the Part must bear a rate of interest that is equal to the rate determined by the Secretary of the Treasury, taking into consideration current market yields outstanding marketable obligations of the United States of comparable maturity. This rate will be determined separately for each drawdown of the loan.

(c) A loan provided under this part may be subject to a deferral in repayment of principal for not more than 5 years after the date on which the Eligible facility that is built or installed as a result of the Eligible Project first begins operations, as determined by the Secretary.

(d)(1) The performance of all of the Borrower's obligations under the Loan Documents shall be secured by, and shall have the priority in, such Security as provided for within the terms and conditions of the Loan Documents.

(2) Accordingly, the rule states that the Secretary must have a first lien or security interest in all property acquired with loan funds. This requirement may be waived only by the Secretary on a non-delegable basis. DOE must also have a lien on any other property of the applicant pledged to secure the loan.

(3) In the event of default, if recoveries from the property and revenues pledged to the repayment of the loan are insufficient to fully repay all principal and interest on the loan, then the Federal Government will have recourse to the assets and revenues of the Borrower to the same extent as senior unsecured general obligations of the Borrower.

(e) The Borrower will be required to pay at the time of the closing of the loan a fee equal to 10 basis points of the principal amount of the loan.

§ 611.108 Perfection of liens and preservation of collateral.

(a) The Agreement and other documents related thereto shall provide that:

(1) DOE and the Applicant, in conjunction with the Federal Financing Bank if necessary, will take those actions necessary to perfect and maintain liens, as applicable, on assets which are pledged as collateral for the loan; and

(2) Upon default by the Borrower, the holder of pledged collateral shall take such actions as DOE may reasonably require to provide for the care, preservation, protection, and maintenance of such collateral so as to enable the United States to achieve maximum recovery from the pledged assets. DOE shall reimburse the holder of collateral for reasonable and appropriate expenses incurred in taking actions required by DOE.

(b) In the event of a default, DOE may enter into such contracts as the Secretary determines are required to preserve the collateral. The cost of such contracts may be charged to the Borrower.

§ 611.109 Audit and access to records.

(a) The Agreement and related documents shall provide that:

(1) DOE in conjunction with the Federal Financing Bank, as applicable, and the Borrower, shall keep such records concerning the project as are necessary, including the Application, Term Sheet, Conditional Commitment, Agreement, mortgage, note, disbursement requests and supporting documentation, financial statements, audit reports of independent accounting firms, lists of all project assets and non-project assets pledged as security for the loan, all off-take and other revenue producing agreements, documentation for all project indebtedness, income tax returns, technology agreements, documentation for all permits and regulatory approvals and all other

documents and records relating to the Eligible Project, as determined by the Secretary, to facilitate an effective audit and performance evaluation of the project; and

(2) The Secretary and the Comptroller General, or their duly authorized representatives, shall have access, for the purpose of audit and examination, to any pertinent books, documents, papers and records of the Borrower or DOE, as applicable. Such inspection may be made during regular office hours of the Borrower or DOE, as applicable, or at any other time mutually convenient.

(b) The Secretary may from time to time audit any or all statements or certificates submitted to the Secretary. The Borrower will make available to the Secretary all books and records and other data available to the Borrower in order to permit the Secretary to carry out such audits. The Borrower should represent that it has within its rights access to all financial and operational records and data relating to the project financed by the loan, and agrees that it will, upon request by the Secretary, exercise such rights in order to make such financial and operational records and data available to the Secretary. In exercising its rights hereunder, the Secretary may utilize employees of other Federal agencies, independent accountants, or other persons.

(c) Loan funds are being expended efficiently and effectively if documentation submitted and audits conducted under this section demonstrate that the borrower is making appropriate progress toward achieving the purpose for which the loan was originally made.

§ 611.110 Assignment or transfer of loans.

(a) The Loan Documents may not be modified, in whole or in part, without the prior written approval of DOE.

(b) Upon prior written approval by DOE and the Federal Financing Bank, a certification by the assignor that the assignee is an Eligible Applicant as described in § 611.100 of this part, and subject to paragraph (c) of this section and other provisions of this part, a Borrower may assign or transfer its interest in a loan provided under this part, including the loan documents, to a party that qualifies as an Eligible Applicant.

(c) The provisions of paragraph (b) of this section shall not apply to transfers which occur by operation of law.

§ 611.111 Default, demand, payment, and collateral liquidation.

(a) In the event that the Borrower has defaulted in the making of required payments of principal or interest, and such default has not been cured within the period of grace provided in the Agreement, DOE may cause the principal amount of the loan, together with accrued interest thereon, and all amounts owed to the United States by Borrower pursuant to the Agreement, to become immediately due and payable by giving the Borrower written notice to such effect.

(b) In the event that the Borrower is in default as a result of a breach of one or more of the terms and conditions of the Agreement, note, mortgage, or other contractual obligations related to the transaction, other than the Borrower's obligation to pay principal or interest on the loan, and DOE determines, in writing, that such a default has materially affected the rights of the parties, the Borrower shall be given the period of grace provided in the Agreement to cure such default. If the default is not cured during the period of grace, DOE may cause the principal amount of the loan, together with accrued interest thereon, and all amounts owed to the United States by Borrower pursuant to the Agreement, to become immediately due and payable by giving the Borrower written notice to such effect.

(c) In the event that the Borrower has defaulted as described in paragraphs (a) or (b) of this section and such default is not cured during the grace period provided in the Agreement, DOE shall notify the U.S. Attorney General. DOE, acting through the U.S. Attorney General, may seek to foreclose on the collateral assets and/or take such other legal action as necessary for the protection of the Government.

(d) If DOE is awarded title to collateral assets pursuant to a foreclosure proceeding, DOE may take action to complete, maintain, operate, or lease the Eligible Facilities, or otherwise dispose of any property acquired pursuant to the Agreement or take any other necessary action which DOE deems appropriate.

(e) In addition to foreclosure and sale of collateral pursuant thereto, the U.S. Attorney General shall take appropriate action in accordance with rights contained in the Agreement to recover costs incurred by the Government as a result of the defaulted loan or other defaulted obligation. Any recovery so received by the U.S. Attorney General on behalf of the Government shall be applied in the following manner: First to the expenses incurred by the U.S. Attorney General and DOE in effecting such recovery; second, to reimbursement of any amounts paid by DOE as a result of the defaulted obligation; third, to any amounts owed to DOE under related principal and interest assistance contracts; and fourth, to any other lawful claims held by the Government on such process. Any sums remaining after full payment of the foregoing shall be available for the benefit of other parties lawfully entitled to claim them.

(f) In the event that DOE considers it necessary or desirable to protect or further the interest of the United States in connection with the liquidation of collateral or recovery of deficiencies due under the loan, DOE will take such action as may be appropriate under the circumstances.

§ 611.112 Termination of obligations.

DOE, the Federal Financing Bank, and the Borrower shall have such rights to terminate the Agreement as are set forth in the loan documents.

Subpart C—Facility/Funding Awards

§ 611.200 Purpose and scope.

This subpart sets forth the policies and procedures applicable to the award and administration of grants by DOE for advanced technology vehicle manufacturing facilities as authorized by section 136(b) of the Energy Independence and Security Act (Pub. L. 110–140).

§ 611.201 Applicability.

Except as otherwise provided by this subpart, the award and administration of grants shall be governed by 10 CFR part 600 (DOE Financial Assistance Rules).

§ 611.202 Advanced Technology Vehicle Manufacturing Facility Award Program.

DOE may issue, under the Advanced Technology Vehicle Manufacturing Facility Award Program, 10 CFR part 611, subpart C, awards for eligible projects.

§ 611.203 Eligibility.

In order to be eligible for an award, an applicant must be either—

(a) An automobile manufacturer that can demonstrate an improved fuel economy as specified in paragraph (b) of section 611.3, or

(b) A manufacturer of a qualifying component.

§ 611.204 Awards.

Awards issued for eligible projects shall be for an amount of no more than 30 percent of the eligible project costs.

§ 611.205 Period of award availability.

An award under section 611.204 shall apply to—

(a) Facilities and equipment placed in service before December 30, 2020; and

(b) Engineering integration costs incurred during the period beginning on December 19, 2007 and ending on December 30, 2020.

§ 611.206 Existing facilities.

The Secretary shall, in making awards to those manufacturers that have existing facilities, give priority to those facilities that are oldest or have been in existence for at least 20 years. Such facilities can currently be sitting idle.

§ 611.207 Small automobile and component manufacturers.

(a) In this section, the term ''covered firm'' means a firm that—

(1) Employs less than 500 individuals; and

(2) Manufactures automobiles or components of automobiles.

(b) *Set Aside.*—Of the amount of funds that are used to provide awards for each fiscal year under this subpart, not less than 10 percent shall be used to provide awards to covered firms or consortia led by a covered firm.

§ 611.208 [Reserved]

§ 611.209 [Reserved]

[FR Doc. E8–26832 Filed 11–6–08; 4:15 pm]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0585; Directorate Identifier 2008–NM–027–AD; Amendment 39–15704; AD 2008–22–09]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747SP Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Boeing Model 747SP series airplanes. This AD requires repetitive lubrication of the rudder tab hinges and repetitive replacement of the rudder tab control rods. This AD results from reports of freeplay-induced vibration on the control surfaces on Boeing Model 727, 737, 757, and 767 airplanes. We are issuing this AD to prevent damage to the control surface structure during flight, which could result in loss of control of the airplane.

DATES: This AD is effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2008.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com;* Internet *https://www.myboeingfleet.com.*

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6426; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to all Boeing Model 747SP series airplanes. That NPRM was published in the **Federal Register** on May 23, 2008 (73 FR 30007). That NPRM proposed to require repetitive lubrication of the rudder tab hinges and repetitive replacement of the rudder tab control rods.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received from the one commenter.

Request To Revise Discussion Section of NPRM

Boeing requests that we revise the Discussion section of the NPRM to remove the statement that the affected control surfaces on Boeing Model 727, 737, 757, and 767 airplanes and Boeing Model 747SP airplanes are similar in design. Boeing states that the only similarity between Model 727, 737, 757, and 767 airplanes and Model 747SP airplanes pertains to flutter-critical unbalanced control surfaces of the identified unsafe condition. Boeing requests that we revise that section of the NPRM to state: ''There have been no reports of freeplay-induced vibration of the 747SP rudder tabs. However, there have been reports pertaining to flutter-critical unbalanced control surfaces on 727, 737, 757 and 767 airplanes. This lubrication and replacement will help prevent conditions which allow excessive freeplay of control surfaces.''

We agree with Boeing that the Discussion section could be clarified as Boeing specified. However, since that section of the preamble does not reappear in the final rule, no change to the final rule is necessary.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

We estimate that this AD affects 7 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this AD. The average labor rate is $80 per work hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per product	Fleet cost
Lubrication	2	None	$160, per cycle	$1,120, per cycle.
Replacement	16	$39,511	40,791, per cycle	285,537, per cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–09 Boeing: Amendment 39–15704. Docket No. FAA–2008–0585; Directorate Identifier 2008–NM–027–AD.

Effective Date

(a) This airworthiness directive (AD) is effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 747SP series airplanes.

Unsafe Condition

(d) This AD results from reports of freeplay-induced vibration on the control surfaces on Boeing Model 727, 737, 757, and 767 airplanes. We are issuing this AD to prevent damage to the control surface structure during flight, which could result in loss of control of the airplane.

Compliance

(e) Comply with this AD within the compliance times specified, unless already done.

Repetitive Lubrication and Replacement

(f) At the applicable compliance time listed in Paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 747–27–2447, dated January 17, 2008, lubricate the rudder tab hinges and replace the rudder tab control rods with new control rods. Repeat the lubrication and replacement thereafter at the applicable repeat interval listed in paragraph 1.E., ''Compliance,'' of the service bulletin. Do all actions in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–27–2447, dated January 17, 2008. Where Boeing Special Attention Service Bulletin 747–27–2447, dated January 17, 2008, specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Kathleen Arrigotti, Aerospace Engineer, Airframe Branch, ANM–120S, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6426; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(h) You must use Boeing Special Attention Service Bulletin 747–27–2447, dated January 17, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com;* Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on October 10, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25689 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–0344; Directorate Identifier 2007–NM–149–AD; Amendment 39–15701; AD 2008–22–06]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Boeing Model 767–200 and –300 series airplanes. This AD requires replacing the wire segments of the four Fuel Quantity Indicating System (FQIS) wire bundles with new, improved wire segments. This AD results from operator inspections of the FQIS wire bundles

that revealed corrosion at the connections between the ground wire and shield of each of the four FQIS wire bundles. We are issuing this AD to prevent this corrosion, which could reduce system protection of the lightning shield and result in loss of the electrical grounding between the lightning shield and the airplane structure. This condition, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

DATES: This AD is effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2008.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail DDCS@boeing.com; Internet *https://www.myboeingfleet.com.*

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Philip Sheridan, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6441; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to certain Boeing Model 767–200 and –300 series airplanes. That NPRM was published in the **Federal Register** on December 19, 2007 (72 FR 71834). That NPRM proposed to require replacing the wire segments of the four Fuel Quantity Indicating System (FQIS) wire bundles with new, improved wire segments.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received from a single commenter.

Request To Clarify the Scope of the NPRM

Boeing asks that we clarify the scope of the NPRM with regard to a specific FQIS design that is affected by corrosion of the FQIS wire bundle. Boeing states that Boeing Alert Service Bulletin 767–28A0064, Revision 2, dated October 27, 2005 (referred to in the NPRM as the appropriate source of service information for accomplishing the specified actions), indicates that the NPRM is applicable only to airplanes on which the Honeywell system is installed; but the name of the affected system is not specified in the NPRM. Simmonds FQIS was installed on certain Model 767 airplanes in production; some airlines retrofitted their airplanes with the Simmonds system, but other airlines continue to use the Honeywell system. Boeing adds that the NPRM should apply only to airplanes on which the Honeywell system is installed.

We acknowledge Boeing's concern that the airplanes affected by this AD should be clearly defined. However, the applicability specified in paragraph (c) of the NPRM already refers to the effectivity in Revision 2 of the referenced service bulletin, which identifies affected airplanes as those having a Honeywell FQIS installed. Therefore, we have made no change to the AD in this regard.

Request To Add Credit Paragraph

Boeing asks that we add a sub-paragraph to paragraph (g) of the NPRM to give credit for airplanes retrofitted with a Simmonds FQIS in accordance with Boeing Service Bulletin 767–28A0043, Revision 2, dated December 20, 2002. Boeing states that this action is also considered an acceptable means to comply with the NPRM.

We do not agree with Boeing. The effectivity specified in Revision 2 of Boeing Alert Service Bulletin 767–28A0064 states, in part, ''This service bulletin is for the airplanes with Honeywell FQIS . . .'' If the FQIS on the airplane has been changed to a Simmonds FQIS, it is no longer a Group 1 airplane, as identified in the effectivity of Boeing Alert Service Bulletin 767–28A0064, Revision 2, and is not affected by this AD. We have made no change to the AD in this regard.

Request To Clarify Costs of Compliance Section

Boeing asks that we identify the origin of the number of affected airplanes specified in the Costs of Compliance section of the NPRM because Boeing is unable to verify the specified number. Boeing states that the referenced service bulletin lists the total number of affected airplanes with a Honeywell FQIS as 433.

We acknowledge Boeing's comment and provide the following clarification. We determined the number of airplanes in the worldwide fleet by extracting the number from the fleet database. We agree with Boeing that the number of worldwide airplanes referenced in the ''Costs of Compliance'' section of the NPRM should agree with the number referenced in Boeing Alert Service Bulletin 767–28A0064, Revision 2, which was developed using Boeing's records of Model 767 airplanes equipped with a Honeywell FQIS. Changing the number of worldwide airplanes will not affect the cost estimate in the AD. Therefore, we have changed the number of affected worldwide airplanes to 433 in the ''Costs of Compliance'' section below. The number of airplanes of U.S. registry remains the same.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are 433 airplanes of the affected design in the worldwide fleet. This AD affects about 169 airplanes of U.S. registry. The replacement takes about 42 work hours per airplane, at an average labor rate of $80 per work hour. Required parts will cost about $1,756 per airplane. Based on these figures, the estimated cost of the AD for U.S. operators is $864,604, or $5,116 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in

air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–06 Boeing: Amendment 39–15701. Docket No. FAA–2007–0344; Directorate Identifier 2007–NM–149–AD.

Effective Date

(a) This airworthiness directive (AD) is effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–200 and –300 series airplanes, certificated in any category; as identified in Boeing Alert Service Bulletin 767–28A0064, Revision 2, dated October 27, 2005.

Unsafe Condition

(d) This AD results from operator inspections of the Fuel Quantity Indicating System (FQIS) wire bundles that revealed corrosion at the connections between the ground wire and shield of each of the four FQIS wire bundles. We are issuing this AD to prevent this corrosion, which could reduce system protection of the lightning shield and result in loss of the electrical grounding between the lightning shield and the airplane structure. This condition, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 36 months after the effective date of this AD: Replace the wire segments of the four FQIS wire bundles with new, improved wire segments, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–28A0064, Revision 2, dated October 27, 2005.

Credit for Actions Done Using Previous Service Information

(g) Actions accomplished before the effective date of this AD in accordance with Boeing Alert Service Bulletin 767–28A0064, Revision 1, dated February 21, 2002, are considered acceptable for compliance with the corresponding actions specified in this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Philip Sheridan, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6441; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Material Incorporated by Reference

(i) You must use Boeing Alert Service Bulletin 767–28A0064, Revision 2, dated October 27, 2005, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com;* Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on October 9, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25308 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28160; Directorate Identifier 2007–NM–006–AD; Amendment 39–15703; AD 2008–22–08]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757–200 and 757–300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Boeing Model 757–200 and 757–300 series airplanes. This AD requires installing a bonding jumper between a ground and the clamp on the tube of the forward and aft gray water composite drain masts. For certain airplanes, this AD requires inspecting existing aft bonding jumper assemblies that might be too short, repair if necessary, and replacing the bonding jumper assembly with a new, longer bonding jumper assembly if necessary. This AD results from a report of charred insulation blankets and burned wires around the forward gray water composite drain mast found during an inspection of the forward cargo compartment on a Model 767–300F airplane. We are issuing this AD to prevent a fire near a composite drain mast and possible disruption of the electrical power system due to a lightning strike on a composite drain mast, which could result in the loss of

several functions essential for safe flight.

DATES: This AD is effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2008.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com*; Internet *https://www.myboeingfleet.com*.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Nicholas Wilson, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6476; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a supplemental notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to certain Boeing Model 757–200 and 757–300 series airplanes. That supplemental NPRM was published in the **Federal Register** on April 8, 2008 (73 FR 19015). That supplemental NPRM proposed to require installing a bonding jumper between a ground and the clamp on the tube of the forward and aft gray water composite drain masts. For certain airplanes, that supplemental NPRM also proposed to require inspecting existing aft bonding jumper assemblies that might be too short, repair if necessary, and replacing the bonding jumper assembly with a new, longer bonding jumper assembly if necessary.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

Support for the AD

Boeing concurs with the contents of the supplemental NPRM. Continental Airlines has no objection to the supplemental NPRM. Northwest Airlines (NWA) is in general concurrence with the modification requirements and concurs with the 60-month compliance time. The Air Transport Association (ATA), on behalf of member airlines, states that its members agree with the intent of the NPRM.

Request To Have Service Information Revised

American Airlines (AAL) requests that Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007, be revised to change the pilot hole dimensions in Figure 2, Sheet 2. (We referred to Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007, as the appropriate source of service information for the proposed actions in the NPRM.) AAL points out that the new bracket is provided without pilot holes, but the service bulletin specifies the hole location: ''Tolerance on linear dimensions, other than rivet and bolt edge margins, is plus or minus 0.03 inch.'' AAL is concerned that it may be an unreasonable expectation, within the on-aircraft environment in which the work is being performed, to locate the holes in the bracket to within 0.03 inch of the specified location. Therefore, AAL recommends that the service bulletin be revised to change the hole location dimensions to be ''0.43 minimum.'' As a supporting argument for this change, AAL points out that the new grounding bracket is installed in a different location to meet the same intent for the forward drain mast and does not include dimensional location information, which AAL believes implies that the hole location in the bracket is not critical to meeting the intent of the service bulletin.

While we do agree that the on-airplane environment can sometimes be a difficult place to work, we disagree that the service bulletin should be revised as requested by AAL. Boeing has pointed out that the edge margin requirement for the fasteners on the bonding bracket is not as critical as the placement of the fastener through stringer S–25 right. This fastener location must be drilled to within 0.35 inch, plus or minus 0.03 inch, from the top edge of the stringer on the airplane. If it is possible to maintain this drawing requirement for on-airplane installation, it should also be possible to maintain the edge margin requirements for the bonding bracket. We have confirmed that Boeing has no plans to revise the service bulletin to change the pilot hole dimensions in Figure 2, Sheet 2. We have not changed the AD in this regard.

Request To Revise the Costs of Compliance

The ATA, on behalf of NWA, requests that we revise the proposed Costs of Compliance provided in the supplemental NPRM. NWA states that Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007, estimates 5.35 work-hours to do the proposed modification. NWA considers this estimate to be low because of the limited access to the area to be modified. Further, NWA notes that the cost estimate provided in the supplemental NPRM reduced the work-hour estimate to only 2 work-hours. Therefore, NWA believes that we have underestimated the costs of compliance imposed on operators.

We do not agree to revise the proposed work-hour estimate. The work-hour estimate of 5.35 pointed out by NWA includes time necessary for access and close. The cost information below describes only the direct costs of the specific actions required by this AD. Based on the best data available, the manufacturer provided the number of work-hours (2) necessary to do the required actions. This number represents the time necessary to perform only the actions actually required by this AD.

We recognize that, in doing the actions required by an AD, operators might incur incidental costs in addition to the direct costs. The cost analysis in AD rulemaking actions, however, typically does not include incidental costs such as the time required to gain access and close up, time necessary for planning, or time necessitated by other administrative actions. Those incidental costs, which might vary significantly among operators, are almost impossible to calculate. We have not changed the AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 83 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour ($)	Parts ($)	Cost per airplane ($)	Number of U.S.-registered airplanes	Fleet cost ($)
Bonding jumper installation	2	80	[1]392	944	70	66,080
Inspection of existing bonding jumper installation in bulk cargo compartment	1	80	392	472	Up to 70	Up to 33,040

[1] Per kit (1 kit per drain mast).

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–08 Boeing: Amendment 39–15703. Docket No. FAA–2007–28160; Directorate Identifier 2007–NM–006–AD.

Effective Date

(a) This airworthiness directive (AD) is effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 757–200 and 757–300 series airplanes, certificated in any category; as identified in Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007.

Unsafe Condition

(d) This AD results from a report of charred insulation blankets and burned wires around the forward gray water composite drain mast found during an inspection of the forward cargo compartment on a Model 767–300F airplane. We are issuing this AD to prevent a fire near a composite drain mast and possible disruption of the electrical power system due to a lightning strike on a composite drain mast, which could result in the loss of several functions essential for safe flight.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Bonding Jumper Installation

(f) Except as provided by paragraph (g) of this AD: Within 60 months after the effective date of this AD, install a bonding jumper between a ground and the clamp on the tube of the forward and aft gray water composite drain mast, in accordance with Parts 1 and 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007.

Existing Bonding Jumper Inspection

(g) For airplanes on which the bonding jumper was installed on the aft drain mast in accordance with Boeing Special Attention Service Bulletin 757–30–0024, dated July 24, 2006: Within 60 months after the effective date of this AD, do a general visual inspection of the aft bonding jumper assembly for signs of riding (chafing), in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007 (''the service bulletin''). If no riding damage is found, no further action is required by this AD for the aft drain mast. If riding damage is found, before further flight do the actions specified in paragraphs (g)(1) and (g)(2) of this AD. Doing the actions specified in this paragraph terminates the requirement to install the bonding jumper on the aft drain mast specified in paragraph (f) of this AD.

(1) Repair any riding damage found in accordance with the service bulletin.

(2) Remove the existing bonding jumper assembly and install a new, longer bonding jumper assembly in accordance with Part 3 of the Accomplishment Instructions of the service bulletin. As an option to the longer bonding jumper assembly, operators may remove the bracket, fill the holes in the stringer, and restore the finish in accordance with Part 3 of the Accomplishment Instructions of the service bulletin; and install the ground bracket and jumper assembly in accordance with Part 2 of the Accomplishment Instructions of the service bulletin.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Nicholas Wilson, Aerospace Engineer, Cabin

Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 917–6476; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Material Incorporated by Reference

(i) You must use Boeing Special Attention Service Bulletin 757–30–0024, Revision 1, dated October 25, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com*; Internet *https://www.myboeingfleet.com*.

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on October 10, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25636 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0151; Directorate Identifier 2007–NM–347–AD; Amendment 39–15708; AD 2008–22–12]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Boeing Model 727 airplanes. This AD requires repetitive inspections for any crack in the area of the elevator side fitting/hinge fitting joint and for any crack or elongation inside and outside of the holes in the clevis and in the lug, corrective actions if necessary, and other specified actions. This AD results from reports of elongated holes and cracks found in the lugs of the attachment fittings of the elevator quadrant upper support assembly at the tip of the vertical fin. We are issuing this AD to detect and correct damage to the aft attachment lugs of the elevator quadrant support assembly that could lead to failure of the lugs. This condition could accelerate wear elsewhere in the elevator control system, which could reduce the crew's ability to maintain safe flight.

DATES: This AD is effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2008.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com;* Internet *https://www.myboeingfleet.com.*

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 917–6577; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to all Boeing Model 727 airplanes. That NPRM was published in the **Federal Register** on February 8, 2008 (73 FR 7489). That NPRM proposed to require repetitive inspections for any crack in the area of the elevator side fitting/hinge fitting joint and for any crack or elongation inside and outside of the holes in the clevis and in the lug, corrective actions if necessary, and other specified actions.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received from the two commenters.

Support for the NPRM

Boeing concurs with the NPRM.

Request To Extend Compliance Time

FedEx requests that we extend the compliance time from 18 months to 30 months for doing the initial inspections of the side and hinge fittings of the elevator control quadrant upper support assembly. FedEx states that, prior to issuance of the AD, it will take immediate action to accomplish the inspections within the required timetable, but that the 18-month compliance time will likely cause FedEx to do the inspections outside of scheduled heavy maintenance. FedEx, therefore, requests an extension of the compliance time, so that it may accomplish the initial inspections for its entire fleet during its next scheduled C-check. FedEx states that it prefers to do the inspections at a maintenance facility during a scheduled heavy maintenance check because of the difficulty associated in providing safe and adequate access to the inspection areas, the availability of the requisite tooling, and the presence of skilled mechanics.

FedEx also requests that we extend the calendar time from 24 months to 30 months for doing the repetitive inspections. (The NPRM proposed accomplishing those inspections within 24 months, 4,000 flight hours, or 3,000 flight cycles, whichever occurs first.) FedEx states that an increase in calendar time should provide an equivalent level of safety because it operates its airplanes at a low, daily-utilization rate, thereby, keeping the flight cycle and flight hour count significantly below the proposed requirement, even after 30 months of calendar time has elapsed. FedEx also states that increasing the calendar time for the repetitive inspections in this way will allow FedEx to accomplish the inspections within its heavy maintenance schedule.

We disagree with the FedEx's request to extend the compliance times for the initial inspection and repetitive interval.

In developing appropriate compliance times for these actions, we considered the urgency associated with the subject unsafe condition, the average utilization rate of the affected fleet, and the practical aspect of accomplishing the required actions within a period of time that corresponds to the normal scheduled maintenance for most affected operators. Although FedEx did not submit any technical data to support its request, its airplane utilization rate might possibly support an extension in the compliance time. However, FedEx's airplane utilization rate might not be typical for most operators, and we believe that the required compliance times specified in the referenced service bulletins coincides with most operators' utilization rates. If FedEx's airplane utilization rate and maintenance program for the inspection area prove that the new compliance time would provide an acceptable level of safety, FedEx may apply for an AMOC according to the provisions in paragraph (i) of this AD. We have not changed the AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

We estimate that this AD affects 401 airplanes of U.S. registry. We also estimate that it takes about 2 work-hours per product to comply with this AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $64,160, or $160 per product, per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–12 Boeing: Amendment 39–15708. Docket No. FAA–2008–0151; Directorate Identifier 2007–NM–347–AD.

Effective Date

(a) This airworthiness directive (AD) is effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of elongated holes and cracks found in the lugs of the attachment fittings of the elevator quadrant upper support assembly at the tip of the vertical fin. We are issuing this AD to detect and correct damage to the aft attachment lugs of the elevator quadrant support assembly that could lead to failure of the lugs. This condition could accelerate wear elsewhere in the elevator control system, which could reduce the crew's ability to maintain safe flight.

Compliance

(e) Comply with this AD within the compliance times specified, unless already done.

Repetitive Inspections and Corrective/Other Specified Actions

(f) At the applicable compliance times specified in paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0092, dated June 4, 2007, except as provided by paragraph (g) of this AD: Do the detailed inspection for any crack in the area of the elevator side fitting/hinge fitting joint, detailed inspections for elongation inside and outside of the holes in the clevis and in the lug, and high frequency eddy current (HFEC) inspections for any crack inside and outside of the holes in the clevis and in the lug, and do all the applicable corrective actions and other specified actions, by accomplishing all of the applicable actions specified in the Accomplishment Instructions of the service bulletin, except as provided by paragraph (h) of this AD. Repeat the inspections thereafter at the applicable intervals specified in paragraph 1.E. of the service bulletin. Accomplishing the repair or modification specified in Part 3 of the service bulletin terminates only the repetitive inspections specified in Part 2 of the service bulletin.

Exceptions to Compliance Times

(g) Where paragraph 1.E. of Boeing Special Attention Service Bulletin 727–55–0092, dated June 4, 2007, specifies counting the compliance time from ''. . . the date on this service bulletin,'' this AD requires counting the compliance time from the effective date of this AD. Where paragraph 1.E. of the service bulletin specifies a compliance time of ''. . . 18 months . . . '' or ''24 months . . .,'' this AD requires a compliance time of 30 months.

Exception to Corrective Actions

(h) If any damage beyond the repair limits or any crack is found in the area of the elevator side fitting/hinge fitting joint during any inspection required by this AD, and Boeing Special Attention Service Bulletin 727–55–0092, dated June 4, 2007, specifies to contact Boeing for appropriate action: Before further flight, repair the crack using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6577; fax (425) 917–6590; has the

authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(j) You must use Boeing Special Attention Service Bulletin 727–55–0092, dated June 4, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207; telephone 206–544–9990; fax 206–766–5682; e-mail *DDCS@boeing.com;* Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on October 9, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25686 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0849; Directorate Identifier 2008–NM–080–AD; Amendment 39–15709; AD 2008–22–13]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Two operators of A300 aircraft fitted with General Electric (GE) CF6–50 engine series have reported cracks on the lower side of Rib 5 in the pylon box.

* * * * *

Investigations disclosed that these cracks are due to the stresses resulting from the pressure applied by the thrust reverser cowl bumpers.

* * * * *

Cracking of the engine pylons could result in reduced structural integrity of the engine support structure. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 17, 2008.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on August 7, 2008 (73 FR 45891). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Two operators of A300 aircraft fitted with General Electric (GE) CF6–50 engine series have reported cracks on the lower side of Rib 5 in the pylon box.

The concerned area is similar on A310 aircraft fitted with GE CF6–80A or CF6–80C series engines.

Investigations disclosed that these cracks are due to the stresses resulting from the pressure applied by the thrust reverser cowl bumpers.

As a result of the A310 Extended Service Goal (ESG) study, an inspection programme of this area is required by this Airworthiness Directive (AD).

A similar inspection programme is being contemplated for A300 and A300–600 series aircraft.

Cracking of the engine pylons could result in reduced structural integrity of the engine support structure. Corrective actions include modifying the Rib 5 in the pylon box. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a **Note** within the AD.

Costs of Compliance

We estimate that this AD will affect about 33 products of U.S. registry. We also estimate that it will take about 8 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $21,120, or $640 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs'', describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements''. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify this AD:

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. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–13 Airbus: Amendment 39–15709. Docket No. FAA–2008–0849; Directorate Identifier 2008–NM–080–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A310–203, –204, and –304 airplanes, all serial numbers, certificated in any category; excluding airplanes that have received Airbus Modification 11110 during production or that have been modified in service in accordance with Airbus Service Bulletin A310–54–2032 (Airbus Modification 11109).

Subject

(d) Air Transport Association (ATA) of America Code 54: Nacelles/Pylons.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Two operators of A300 aircraft fitted with General Electric (GE) CF6–50 engine series have reported cracks on the lower side of Rib 5 in the pylon box.

The concerned area is similar on A310 aircraft fitted with GE CF6–80A or CF6–80C series engines.

Investigations disclosed that these cracks are due to the stresses resulting from the pressure applied by the thrust reverser cowl bumpers.

As a result of the A310 Extended Service Goal (ESG) study, an inspection programme of this area is required by this Airworthiness Directive (AD).

A similar inspection programme is being contemplated for A300 and A300–600 series aircraft.

Cracking of the engine pylons could result in reduced structural integrity of the engine support structure. Corrective actions include modifying the Rib 5 in the pylon box.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Perform a high frequency eddy current (HFEC) inspection and a detailed visual inspection on the lower side of Rib 5 of the left-hand and right-hand pylons, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310–54–2036, Revision 02, dated September 28, 2007. Do the inspections at the times specified in paragraph (f)(1)(i) or (f)(1)(ii) of this AD, as applicable.

(i) For Model A310–203 and –204 airplanes: Inspect at the later of the times specified in paragraphs (f)(1)(i)(A) and (f)(1)(i)(B) of this AD.

(A) Prior to the accumulation of 40,000 total flight cycles or 60,000 total flight hours, whichever occurs first.

(B) Within 250 flight hours after the effective date of this AD.

(ii) For Model A310–304 airplanes: Inspect at the later of the times specified in paragraphs (f)(1)(ii)(A) and (f)(1)(ii)(B) of this AD.

(A) Prior to the accumulation of 35,000 total flight cycles or 60,000 total flight hours, whichever occurs first.

(B) Within 250 flight hours after the effective date of this AD.

(2) If no crack is found during any inspection required by paragraph (f)(1) of this AD: Repeat the inspections thereafter at intervals not to exceed 15,000 flight hours.

(3) If any crack is found during any inspection required by paragraph (f)(1) of this AD: Before further flight, modify Rib 5 in the pylon box in accordance with the Accomplishment Instructions of Airbus Service Bulletins A310–54–2032, Revision 01, dated October 8, 2007. Accomplishment of this modification ends the repetitive inspections required by this AD.

(4) Accomplishment of the HFEC and detailed visual inspections before the effective date of this AD in accordance with Airbus Service Bulletin A310–54–2036, Revision 01, dated September 14, 1999, meets the corresponding requirements of paragraph (f) of this AD.

(5) Accomplishment of the modification before the effective date of this AD in accordance with Airbus Service Bulletin A310–54–2032, dated May 29, 1996, meets the corresponding requirements of paragraph (f) of this AD.

(6) Submit the initial inspection results specified in Appendix 01 of Airbus Mandatory Service Bulletin A310–54–2036, Revision 02, dated September 28, 2007, at the time specified in paragraph (f)(6)(i) or (f)(6)(ii) of this AD.

(i) If the inspections were done after the effective date of this AD: Within 30 days after accomplishing the inspections required by paragraph (f)(1) of this AD.

(ii) If the inspections were done prior to the effective date of this AD: Within 30 days after the effective date of this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: Although the MCAI allows further flight after cracks are found during compliance with the required action, this AD requires that you repair the crack(s) before further flight.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2008–0066, dated March 31, 2008; Airbus Service Bulletin A310–54–2032, Revision 01, dated October 8, 2007; and Airbus Mandatory Service Bulletin A310–54–2036, Revision 02, dated September 28, 2007; for related information.

Material Incorporated by Reference

(i) You must use Airbus Service Bulletin A310–54–2032, Revision 01, dated October 8, 2007; and Airbus Mandatory Service Bulletin A310–54–2036, including Appendix 01, Revision 02, dated September 28, 2007; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 33 33; Internet *http://www.airbus.com*.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on October 9, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25767 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0667; Directorate Identifier 2008–NM–009–AD; Amendment 39–15717; AD 2008–22–20]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200, A330–300, and A340–300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During fatigue tests (EF3) on the A340–600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330–200/–300 and A340–300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

* * * * *

The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective December 17, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 17, 2008.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on June 24, 2008 (73 FR 35603). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

During fatigue tests (EF3) on the A340–600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330–200/–300 and A340–300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

[T]o allow early detection of cracks, which could [prevent] possible crack propagation and consequently to maintain the structural integrity of the upper shell structure between FR80 and FR86, this Airworthiness Directive (AD) mandates an inspection program [for cracking] of this area using a high frequency eddy current (HFEC) method, and a modification to improve the upper shell structure.

The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. Corrective actions include doing eddy current inspections for cracking of certain fastener rows, and contacting Airbus for repair instructions and repairing. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received.

Request To Allow Flight With Cracks

Northwest Airlines (NWA) requests that we reconsider eliminating the provision for flight with certain cracks. NWA states that the MCAI and Airbus service bulletins (that were referenced in the NPRM as appropriate sources of service information) provide for flight with certain cracks if follow-on inspections are accomplished in accordance with the service bulletin.

We do not concur. Our policy specifies the requirement to repair known cracks before further flight (though we may make exceptions to this policy in certain cases of unusual need, as discussed below). This policy is based on the fact that such damaged airplanes do not conform to the FAA-certificated type design and, therefore, are not airworthy until a properly approved repair is made. While recognizing that repair deferrals might be necessary at times, our policy is intended to minimize adverse human factors relating to the lack of reliability of long-term repetitive inspections, which might reduce the safety of the type-certificated design if such repair deferrals are practiced routinely.

As noted above, we may make an exception to this policy in certain cases, if there is an unusual need for a temporary deferral. Unusual needs include such circumstances as legitimate difficulty in acquiring parts to accomplish repairs. Under such conditions, we may allow a temporary deferral of the repair, subject to a stringent inspection program acceptable to the FAA. We acknowledge that the manufacturer has specified inspection intervals that are intended to allow continued operation with known cracks, and to prevent the need for extensive repairs. However, since we are not aware of any unusual need for repair deferral in regard to this AD, we have not evaluated these inspection intervals.

Under the provisions of paragraph (g)(1) of this AD, we will consider requests for approval of an AMOC if sufficient data are submitted to substantiate that temporary deferral of repair with follow-on inspections would provide an acceptable level of safety. We have not changed the AD in this regard.

Actions Since NPRM Was Issued

Airbus has issued revisions to two service bulletins referenced in the NPRM as appropriate sources of service information. Airbus Mandatory Service Bulletins A330–53–3168 and A340–53–4174, both Revision 01, both dated February 15, 2008, are essentially the same as the original versions of those service bulletins except for clarifications, and no additional work is required for airplanes modified per the original issue. We have changed the references in paragraphs (f)(1), (f)(2)(i), and (h) of this AD to include Revision 01 of those service bulletins, and added paragraph (f)(4) to this AD to give credit for actions performed according to the original issues.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a **Note** within the AD.

Costs of Compliance

We estimate that this AD will affect about 26 products of U.S. registry. We also estimate that it will take about 202 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Required parts will cost about $19,020 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $914,680, or $35,180 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify this AD:

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. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2008–22–20 Airbus: Amendment 39–15717. Docket No. FAA–2008–0667; Directorate Identifier 2008–NM–009–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 17, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330–200, A330–300, and A340–300 series airplanes; certificated in any category; all certified models, all serial numbers; on which Airbus Modification 44205 has been embodied in production, except those on which Airbus Modification 52974 or 53223 has been embodied in production.

Subject

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During fatigue tests (EF3) on the A340–600, damages were found in longitudinal doubler at VTP [vertical tail plane] attachment cutout between Frame (FR) 80 and FR86. This damage occurred between 58341 and 72891 simulated Flight Cycles (FC).

Due to the higher Design Service Goal and different design (e.g., doubler thickness) [of the] A330–200/–300 and A340–300 aircraft series, the damage assessment concluded [there was] potential impact on [the airplanes specified in the] applicability.

[T]o allow early detection of cracks, which could [prevent] possible crack propagation and consequently to maintain the structural integrity of the upper shell structure between FR80 and FR86, this Airworthiness Directive (AD) mandates an inspection program [for cracking] of this area using a high frequency eddy current (HFEC) method, and a modification to improve the upper shell structure.

The unsafe condition is crack propagation in the VTP attachment cutout, which could reduce airplane structural integrity in the tail section. Corrective actions include doing eddy current inspections for cracking of certain fastener rows, and contacting Airbus for repair instructions and repairing.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) For Airbus Model A330–300 and A340–300 series airplanes, except Model A340–300 weight variant (WV) 027 airplanes: At the applicable compliance time specified in paragraph (f)(2) of this AD, perform a HFEC inspection of the upper shell structure between FR80 and FR86, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(i) If no crack is detected, repeat the inspection thereafter within the intervals specified in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(ii) If any crack is detected during any inspection required by this AD: Before next flight, contact Airbus for repair instructions and do applicable repairs.

(iii) Doing the modification of the upper shell structure in accordance with Airbus Service Bulletin A330–53–3159 or A340–53–4165, both dated September 19, 2007, as applicable, ends the inspections required by paragraph (f)(1) of this AD.

(2) Do the actions required by paragraph (f)(1) of this AD at the later of the compliance times specified in paragraph (f)(2)(i) and (f)(2)(ii) of this AD.

(i) Within the compliance times specified in paragraph 1.E.(2) of Airbus Mandatory Service Bulletin A330–53–3168 or A340–53–4174, both Revision 01, both dated February 15, 2008, as applicable.

(ii) Within 3 months after the effective date of this AD.

(3) At the applicable time specified in paragraphs (f)(3)(i), (f)(3)(ii), and (f)(3)(iii) of this AD or within 3 months after the effective date of this AD, whichever occurs later, modify the upper shell structure between FR80 and FR86 (including doing eddy current inspections for cracking of certain fastener rows and applicable corrective actions) in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3160, dated July 9, 2007; or Airbus Mandatory Service Bulletin A340–53–4172, dated July 10, 2007; as applicable. Do all applicable corrective actions before further flight.

(i) For Model A330–200 airplanes, WV 020 through WV 027: Prior to the accumulation of 13,500 total flight cycles.

(ii) For Model A330–200 airplanes, WV 050 through WV 055: Prior to the accumulation of 10,700 total flight cycles or 59,300 total flight hours, whichever occurs first.

(iii) For Model A340–300 airplanes, WV 027: Prior to the accumulation of 14,200 total flight cycles.

(4) Inspections accomplished before the effective date of this AD according to Airbus Mandatory Service Bulletins A330–53–3168 and A340–53–4174, both dated September 19, 2007, as applicable, are considered acceptable for compliance with the corresponding actions specified in this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: Although the MCAI allows further flight after cracks are found during compliance with the required action, this AD requires that you repair the crack(s) before further flight.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested, using the procedures found in 14 CFR 39.19. Send information to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2007–0284, dated November 12, 2007, and the service bulletins specified in Table 1 of this AD, for related information.

TABLE 1—SERVICE INFORMATION

Airbus service information	Revision	Date
Mandatory Service Bulletin A330–53–3160	Original	July 9, 2007.
Mandatory Service Bulletin A330–53–3168	01	February 15, 2008.
Mandatory Service Bulletin A340–53–4172	Original	July 10, 2007.
Mandatory Service Bulletin A340–53–4174	01	February 15, 2008.
Service Bulletin A330–53–3159	Original	September 19, 2007.

TABLE 1—SERVICE INFORMATION—Continued

Airbus service information	Revision	Date
Service Bulletin A340–53–4165	Original	September 19, 2007.

Material Incorporated by Reference

(i) You must use the service information specified in Table 2 of this AD to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 33 33; Internet *http://www.airbus.com*.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

TABLE 2—MATERIAL INCORPORATED BY REFERENCE

Airbus service information	Revision	Date
Mandatory Service Bulletin A330–53–3160	Original	July 9, 2007.
Mandatory Service Bulletin A330–53–3168	01	February 15, 2008.
Mandatory Service Bulletin A340–53–4172	Original	July 10, 2007.
Mandatory Service Bulletin A340–53–4174	01	February 15, 2008.
Service Bulletin A330–53–3159	Original	September 19, 2007.
Service Bulletin A340–53–4165	Original	September 19, 2007.

Issued in Renton, Washington, on October 20, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–25787 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2008–N–0561]

Maximum Civil Money Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a new regulation to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended. The last adjustment was published in the **Federal Register** of July 20, 2004 (69 FR 43299), and the FCPIAA requires Federal agencies to adjust their civil money penalties at least once every 4 years. This rule does not adjust the civil money provisions enacted by the Food and Drug Administration Amendments Act of 2007 (FDAAA). We are using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This rule is effective March 27, 2009, without further notice, unless FDA receives significant adverse comment by January 26, 2009. If we receive no timely significant adverse comments, we will publish a document in the **Federal Register** before February 25, 2009, confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a document in the **Federal Register** withdrawing this direct final rule before March 27, 2009.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0561, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. FDA–2008–N–0561 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments

regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In general, the FCPIAA (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as: ''* * * the percentage (if any) for each civil monetary penalty by which—(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law''(28 U.S.C. 2461 note, section 5(b)).

The FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the first adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as: ''any penalty, fine, or other sanction that—(A)(i) is for a specific monetary amount as provided by Federal law; or (ii) has a maximum amount provided for by Federal law; and (B) is assessed or enforced by an agency pursuant to Federal law; and (C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts'' (28 U.S.C. 2461 note, section 3(2)).

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

In the **Federal Register** of July 20, 2004 (69 FR 43299), we published a final rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The final rule amended our regulations governing civil money penalties hearings found at part 17 (21 CFR part 17) to establish a new § 17.2 entitled ''Maximum penalty amounts'' to show the maximum civil monetary penalty amounts that were adjusted under the FCPIAA. The final rule also revised § 17.1, which lists statutory provisions authorizing civil money penalties governed by the civil money penalty regulations as of August 28, 1995, updating the statutory citations.

FDA is publishing this rule as a direct final rule without prior proposal and comment because we view this as a noncontroversial amendment and anticipate no significant adverse comment. This rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a regulation implementing inflation adjustments for all its civil penalty provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which civil penalties are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. In addition, FDA has made conforming changes to the regulations, which have no substantive effect, to reflect the new penalties prescribed by Congress in FDAAA.

II. What Changes Did We Make?

We revised the list of statutory monetary penalties in § 17.1 to include the new penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended by FDAAA in 2007. These new penalties have been added as new paragraphs (c) and (d). The table in § 17.2 has also been amended to include the new penalties, and the adjusted maximum penalty amounts for the pre-FDAAA penalties have been updated to account for the inflation between June 2004 (the year of the last adjustment) and June 2007 as prescribed by FCPIAA. The per violation amount for 21 U.S.C. 333(f)(1)(A), the per violation per person amount for 21 U.S.C. 360pp(b)(1), and the per violation amount for 42 U.S.C. 263b(h)(3) have not been adjusted because the rounding rules of FCPIAA prevent an inflation adjustment in these cases. The new FDAAA penalties have also not been adjusted because Congress only recently passed FDAAA on September 27, 2007. Finally, the ''Description of the Violation'' column in the table in § 17.2 has been removed, as it is unnecessary for purposes of merely showing the adjustment in penalty amounts.

III. What Does the Direct Final Rule Do?

In brief, the direct final rule:

- Revises § 17.1 to update the statutory citations regarding the new civil monetary penalties prescribed by FDAAA, and
- Revises the table in § 17.2 to include the new FDAAA penalties, and adjusts the pre-FDAAA maximum civil penalty amounts for inflation as prescribed by FCPIAA.

IV. Environmental Impact

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

V. Paperwork Reduction Act 1995

We conclude that the civil monetary penalties adjustments in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and

benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule simply adjusts the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

■ 2. Section 17.1 is amended by redesignating paragraphs (c) through (g) as paragraphs (e) through (i) and by adding new paragraphs (c) and (d) to read as follows:

§ 17.1 Scope.

* * * * *

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

* * * * *

■ 3. Section 17.2 is revised to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period	2008	1,200,000
333(b)(3)	110,000	Per violation	2008	120,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000
333(f)(2)(A)	55,000	Per individual	2008	60,000
333(f)(2)(A)	275,000	Per ''any other person''	2008	300,000
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted)
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected	2007	10,000 (not adjusted)
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted)
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2007	250,000 (not adjusted)
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for ''any other person''	2008	1,200,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26866 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–P–0205 (formerly Docket No. 2004P–0464)]

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of Monday, September 29, 2008 (73 FR 56477). The final rule was published with an inadvertent error in the ''Analysis of Economic Impacts'' section. This document corrects that error.

DATES: This correction is effective: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Office of Nutrition, Labeling, and Dietary Supplements (HFS–830), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22730, appearing on page 56477 in the **Federal Register** of September 29, 2008, the following correction is made:

1. On page 56481, in the second column, starting in the forth line, the sentence ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.'' is corrected to read ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency believes that the final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26868 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 578

Decorations, Medals, Ribbons, and Similar Devices

AGENCY: Department of the Army, DOD.

ACTION: Final rule; removal.

SUMMARY: This action removes 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices. The Department of the Army has determined that the rules prescribing policy and criteria for military awards and the administrative instructions for processing military awards are not required to be published in the Code of Federal Regulations (CFR) because they are not generally applicable and have no legal effect per 44 U.S.C. 1505.

DATES: Effective date November 12, 2008.

ADDRESSES: U.S. Army Human Resources Command, *ATTN:* AHRC–PDP–A, 200 Stovall Street, Alexandria, VA 22332–0471.

FOR FURTHER INFORMATION CONTACT: Mr. Les Plooster, Policy Section, Military Awards Branch, 703–325–4761.

SUPPLEMENTARY INFORMATION: The Deputy Chief of Staff, G–1, is the proponent for the regulation represented in 32 CFR Part 578. The objective of the Department of the Army Military Awards Program is to provide tangible recognition for acts of valor, exceptional service or achievement, special skills or qualifications, and acts of heroism not involving actual combat. Implementation of the program is a command responsibility, with the goal of fostering mission accomplishment by recognizing excellence of both military and civilian members of the force and motivating them to high levels of performance and service. As such, the program does not have the general applicability and legal effect required to publish rules pertaining to this program in the Code of Federal Regulations.

List of Subjects in 32 CFR Part 578

Decorations, Medals, Awards, Military Personnel.

PART 578—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority of Sec. 3012, Public Law 84–1028, 70A Stat. 157, and 10 U.S.C. 3013, 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices, is removed in its entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–26699 Filed 11–10–08; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

RIN 0651–AC28

[Docket No.: PTO–P–2008–0023]

Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is amending the rules of practice to adjust the transmittal and search fees for international applications filed under the Patent Cooperation Treaty (PCT). The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

DATES: *Effective Date:* The changes to 37 CFR 1.445 are effective on January 12, 2009 and are applicable to any international application having a receipt date that is on or after January 12, 2009.

FOR FURTHER INFORMATION CONTACT: Boris Milef, Legal Examiner, Office of PCT Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–3288; or by mail addressed to: Box Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: The PCT enables United States applicants to file one application (a PCT international application) in a standardized format in English in a Receiving Office (either the United States Patent and Trademark Office or the International Bureau of the World Intellectual Property

Organization (WIPO)) and have that application acknowledged as a regular national or regional filing by PCT member countries. *See* Manual of Patent Examining Procedure (MPEP) § 1801 (8th ed. 2001) (Rev. 7, July 2008). The primary benefit of the PCT system is the ability to delay the expense of submitting papers and fees to the PCT national offices. *See* MPEP § 1893.

The Office acts as a Receiving Office for United States residents and nationals. *See* 35 U.S.C. 361(a), 37 CFR 1.412(a), and MPEP § 1801. A Receiving Office functions as the filing and formalities review organization for PCT international applications. *See* MPEP § 1801. The Office, in its capacity as a Receiving Office, received over 50,000 PCT international applications in each of fiscal years 2006 and 2007. The Office also acts as an International Searching Authority (ISA). *See* 35 U.S.C. 362(a), 37 CFR 1.413(a), and MPEP § 1840. The primary functions of an ISA are to establish: (1) International search reports, and (2) written opinions of the ISA. *See* MPEP § 1840.

The transmittal and search fees for a PCT international application are provided for in 35 U.S.C. 376. *See* 35 U.S.C. 376 (the Office ''may also charge'' a ''transmittal fee,'' ''search fee,'' ''supplemental search fee,'' and ''any additional fees'' (35 U.S.C. 376(a)), and the ''amounts of [these] fees * * * shall be prescribed by the Director'' (35 U.S.C. 376(b)). In addition, 35 U.S.C. 41(d) provides that fee amounts set by the Office ''recover the estimated average cost to the Office of such processing, services, or materials.'' *See* 35 U.S.C. 41(d). The current PCT transmittal, search, and supplemental search fees are set at amounts that do not recover the estimated average cost to the Office of performing these functions for PCT international applications. Therefore, the Office is adjusting the PCT transmittal fee, search fee, and supplemental search fee to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

The Office uses an Activity Based Information (ABI) methodology to determine the estimated average costs on a per process, service, or material basis. The ABI analysis includes compiling the Office costs for a specified activity, including the direct costs (*e.g.*, direct personnel compensation, contract services, maintenance and repairs, communications, utilities, equipment, supplies, materials, and training), an appropriate allocation of direct allocated costs (*e.g.*, rent, program-related automation, and personnel compensation benefits such as medical insurance and retirement), and an appropriate allocation of indirect allocated costs (*e.g.*, general financial and human resource management, non-program specific automation, and general Office expenses). The direct cost for an activity plus its direct allocated costs and indirect allocated costs is the ''fully burdened'' cost for that activity. The ''fully burdened'' cost for an activity is then divided by production measures (number of that activity completed) to arrive at the fully burdened per-unit cost for that activity. The cost for a particular process is then determined by ascertaining which activities occur for the process, and how often each such activity occurs for the process.

The ABI analysis in this final rule is based upon fiscal year 2007 costs, as fiscal year 2007 is the most recent fiscal year for which complete cost and production measure information is available. The Office is adjusting the fiscal year 2007 cost by the change in the Consumer Price Index for All Urban Consumers (CPI–U) between fiscal year 2007 and fiscal year 2009 as the CPI–U is a reasonable basis for determining the changes in Office costs between fiscal year 2007 and fiscal year 2009. Thus, the Office will adjust the fiscal year 2007 costs by five percent to account for the increase in Office costs between fiscal year 2007 and fiscal year 2009 to determine the estimated fiscal year 2009 costs. The Office plans to revalidate these costs every three to five years, and use the CPI–U as the basis for adjustment of these fees in the intervening years as the changes in the CPI–U is a reasonable basis for determining the year-to-year changes in Office costs.

Finally, the fiscal year 2009 cost amounts are rounded by applying standard arithmetic rules to the nearest five dollars for fee setting purposes so that the resulting fee amounts will be convenient to patent users.

The processing of PCT international applications involves the following activities, with the fiscal year 2007 costs of the activity per PCT international application indicated in parentheses: (1) Application capture and initial processing ($20); (2) application scanning ($96); (3) application formalities review ($107); and (4) classification and security review ($7). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of processing a PCT international application was $230. Therefore, the estimated average fiscal year 2009 cost to the Office of processing a PCT international application is $241 ($230 multiplied by 1.05). Accordingly, this final rule sets the transmittal fee at $240.00.

The Office currently prepares an international search report and written opinion for a PCT international application by one of three methods: (1) Transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a), if possible; (2) having an Office examiner prepare the international search report and written opinion; and (3) acquiring the international search report and written opinion from a competitive source.

Obtaining an international search report and written opinion for a PCT international application by transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) involves having Office personnel transcribe the Office action for the prior-filed application into an international search report and written opinion. The Office estimates that the average fiscal year 2007 cost to the Office of this activity per international search report and written opinion was $218.

Acquiring the international search report and written opinion by having an Office examiner prepare the international search report and written opinion involves at least the following activities, with the fiscal year 2007 costs of the activity per international search report and written opinion indicated in parentheses: (1) Fee processing and classification of the application by technology center art unit ($108); and (2) analysis, search of prior art, and preparation of an international search report and written opinion by an Office examiner ($2,284). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of acquiring an international search report and written opinion by having an Office examiner prepare the international search report and written opinion was $2,392.

Acquiring the international search report and written opinion from a competitive source involves the following activities, with the fiscal year 2007 costs of the activity per international search report and written opinion indicated in parentheses: (1) Contract for an international search report and written opinion ($1,837) (direct allocated costs are excluded from this cost amount because the use of Office space is not involved); and (2) contract oversight and quality review of international search report and written opinion ($237). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of acquiring the international search report and written

opinion by acquiring the international search report and written opinion from a competitive source was $2,074.

Preparing an international search report and written opinion for a PCT international application by transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) is a viable option for only an incidental number (five percent) of PCT international applications due to the current pendency to first Office action. Therefore, to meet the time frames established in the PCT, the Office must rely upon having an Office examiner prepare the international search report and written opinion, or acquiring the international search report and written opinion from a competitive source, in the vast majority (ninety-five percent) of PCT international applications. The Office is migrating towards obtaining international search reports and written opinion for a PCT international application from a competitive source in the ninety-five percent of applications for which transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) is not a viable option. Therefore, the fiscal year 2009 average cost of obtaining an international search report and written opinion for a PCT international application is estimated on the basis of the Office transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) in five percent of applications and acquiring the international search report and written opinion from a competitive source in ninety-five percent of applications, resulting in a composite fiscal year 2007 cost of $1,981 ($2,074 multiplied by 0.95 plus $218 multiplied by 0.05). Therefore, the estimated average fiscal year 2009 cost of preparing an international search report and written opinion for a PCT international application is $2,080 ($1,981 multiplied by 1.05). Accordingly, this final rule sets the search fee and supplemental search fee at $2,080.

Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is amended as follows:

Section 1.445: Section 1.445(a)(1) is amended to change the transmittal fee from $300.00 to $240.00. Section 1.445(a)(2) is amended to change the search fee from $1,800.00 to $2,080.00. Section 1.445(a)(3) is amended to change the supplemental search fee from $1,800.00 to $2,080.00.

Response to Comments: The Office published a notice proposing to adjust the transmittal and search fees for international applications filed under the PCT to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications. *See Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees,* 73 FR 34672 (June 18, 2008), 1332 *Off. Gaz. Pat. Office* 295 (July 15, 2008) (proposed rule), and *Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees,* 73 FR 38027 (July 2, 2008), 1332 *Off. Gaz. Pat. Office* 421 (July 29, 2008) (correction).

Comment: The Office received one comment (from the American Intellectual Property Law Association (AIPLA)) in response to the proposed rule making notice. The comment supported the principle that patent users should pay the average costs incurred by the Office in providing services but raised a number of concerns with respect to the proposed changes to the transmittal and search fees. The comment first requested information on how the transmittal and international search fees under § 1.445 were calculated so that the patent user community can determine whether the proposed increases in fees are necessary or reasonable. The comment also stated that the international search fee under § 1.445 overcharges and discriminates against U.S. nationals using the PCT because the costs for search and examination of national applications are subsidized by issue and maintenance fees, and PCT applications from U.S. nationals generally result in national stage applications which will generate issue and maintenance fees to the same extent as other national applications. The comment also stated that the international search fee under § 1.445 overcharges and discriminates against U.S. applicants who file PCT applications claiming priority of an earlier-filed U.S. national application, as such applicants will pay both the full national search fee and the full international search fee thus effectively paying twice for the same search. The comment also questioned why the transmittal fee set forth in § 1.445(a)(1) is higher than transmittal fees charged by other PCT Receiving Offices and suggested that instead of increasing the transmittal fee, the Office should determine how it can perform its Receiving Office functions at costs in line with the rest of the world.

Response: The basis for the estimated average costs to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications has been discussed previously. The patent fee structure set forth in 35 U.S.C. 41 is a combination of specified patent fees (35 U.S.C. 41(a), (b), (d)(1), and (d)(2)(A) through (C)) that cover enumerated processing, services, and materials, and a provision (35 U.S.C. 41(d)(2)) directing the Office to establish fees for all other processing, services, or materials relating to patents that are not otherwise specified in 35 U.S.C. 41. The provisions of 35 U.S.C. 41(d)(2) apply to the PCT fees by the Office under the authority provided in 35 U.S.C. 376. *See* H. Rep. 97–542, at 8 (1982) (noting that the ''other processing'' and ''services'' covered by 35 U.S.C. 41(d)(2) (then 35 U.S.C. 41(d)) include *inter alia* the processing of PCT international applications). The transmittal and international search fees under § 1.445 are not fees specified under 35 U.S.C. 41, but rather are processing or services pertaining to PCT international applications. Thus, 35 U.S.C. 41(d)(2) provides for the Office to set the transmittal and international search fees to recover their estimated average costs to the Office.

The application filing fees (filing, search, and examination fees) for an application under 35 U.S.C. 111(a), which currently total $1090.00 ($545.00 small entity) for an original nonprovisional patent application (other than plant or design), do not recover the Office's costs of initial processing and examination of an application, but rather this cost is subsidized by patent issue and maintenance fees. *See* H.R. Rep. 108–241, at 15 (2003) (noting that the Office's costs of examining applications are subsidized by issue and maintenance fees). 35 U.S.C. 41(a) and (b) provide a fee structure under which the application filing fees for an application under 35 U.S.C. 111(a) are lower than the Office's costs of initial processing and the examination provided for in 35 U.S.C. 132(a) and are subsidized by patent issue and maintenance fees. 35 U.S.C. 41 and 376 do not provide for the Office to establish PCT international stage fees lower than the Office's costs and to subsidize the costs by revenue generated from patent issue and maintenance fees. Rather, 35 U.S.C. 41(d)(2) provides for fees that recover the estimated average cost to the Office of the processing, services, or materials, which is incongruous with setting a fee lower than the cost of the processing, service, or material and to be subsidized by revenue generated from other fees. In any event, since international applications under the PCT do not themselves mature into patents, it is appropriate that the fees

paid in PCT international applications accurately reflect the costs to the Office of the processing, search, and examination of these applications.

The Office provides a reduced search fee for applications entering the national stage under 35 U.S.C. 371 where the search fee has been paid on the PCT international application to the Office as an International Searching Authority. *See* § 1.492(b)(2).

The Office does not provide a reduced search fee for PCT international applications where there has been a prior-filed application under 35 U.S.C. 111(a). As discussed previously, the Office's current pendency to first Office action does not allow for the use of the search in the prior-filed application under 35 U.S.C. 111(a) for the preparation of an international search report and written opinion for a PCT international application for the vast majority of applications, if the Office is to meet the time frames established in the PCT. Thus, the Office generally incurs the cost of conducting separate searches for the PCT international application and the prior-filed application under 35 U.S.C. 111(a) in this situation.

The PCT transmittal fee being adopted in this final rule is lower than what some Receiving Offices charge and higher than what other Receiving Offices charge. What transmittal and search fees other Receiving Offices and International Searching Authorities charge are immaterial. The Office encounters different costs than do other Receiving Offices and International Searching Authorities for a number of reasons beyond the control of the Office. In addition, it is not clear that other Receiving Offices and International Searching Authorities set their transmittal or search fees on a cost-recovery basis as provided for in 35 U.S.C. 41(d)(2).

Rule Making Considerations

A. Final Regulatory Flexibility Analysis

1. Description of the Reasons That Action by the Agency Is Being Considered

The Office is revising the rules of practice to adjust the transmittal and search fees for international applications filed under the PCT. The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Rules

The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications. The changes in this final rule are authorized by 35 U.S.C. 41(d) and 376.

3. Description and Estimate of the Number of Affected Small Entities

The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System code. The Office, however, has formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109 (Nov. 20, 2006), 1313 *Off. Gaz. Pat. Office* 60 (Dec. 12, 2006). This alternate small business size standard is the previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. *See* 13 CFR 121.802. If patent applicants identify themselves on a patent application as qualifying for reduced patent fees, the Office captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, this size standard is not industry-specific. Specifically, the Office's definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) Meets the SBA's definition of a ''business concern or concern'' set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 67112, 1313 *Off. Gaz. Pat. Office* at 63.

The changes in this final rule will apply to any small entity who files a PCT international application in the United States Receiving Office and to any small entity who requests a search by the United States International Searching Authority. The Office received between 52,000 and 53,000 PCT international applications in each of fiscal years 2006 and 2007. There is no provision in 35 U.S.C. 376 (or elsewhere) for a small entity reduction for the transmittal or search fees for a PCT international application. Thus, PCT applicants do not indicate and the Office does not record whether a PCT international application is filed by a small entity or a non-small entity. The Office's PALM and Revenue Accounting and Management (RAM) systems indicate that 12,043 of the PCT international applications in fiscal year 2006 claim priority to a prior application (nonprovisional or provisional) that has small entity status, and that 2,559 of the PCT international applications in fiscal year 2006 do not claim priority to any prior nonprovisional application or provisional application. The Office's PALM and RAM systems indicate that 12,716 of the PCT international applications in fiscal year 2007 claim priority to a prior application (nonprovisional or provisional) that has small entity status, and that 4,016 of the PCT international applications in fiscal year 2007 do not claim priority to any prior nonprovisional application or provisional application.

4. Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Rules, 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

This final rule does not involve any reporting, recordkeeping and other compliance requirements. This final rule only adjusts the PCT transmittal and search fees. As discussed previously, there is no provision in 35 U.S.C. 376 (or elsewhere) for a small entity reduction for the transmittal or search fees for a PCT international

application. The following table (Table 1) indicates the PCT international stage fee, the number of payments of the fee received by the Office in fiscal year 2007 (number of entities who paid the applicable fee in fiscal year 2007), the former fee amount, the revised fee amount, and the net amount of the fee adjustment.

TABLE 1

Fee	Fiscal Year 2007 payments	Former fee amount	Revised fee amount	Fee adjustment
Transmittal fee	54,335	300.00	240.00	(60.00)
Search Fee	30,965	1800.00	2080.00	280.00
Supplemental Search Fee	941	1800.00	2080.00	280.00

The PCT international search fee and supplemental search fee were adjusted from $1,000.00 to $1,800.00 in November of 2007. *See April 2007 Revision of Patent Cooperation Treaty Procedures*, 72 FR 51559 (Sept. 10, 2007), 1323 *Off. Gaz. Pat. Office* 26 (Oct. 2, 2007) (final rule). Thus, the change to the search fee and supplemental search fee in this final rule is a $280.00 increase over the current search fee and supplemental search fee set in November of 2007, and a $1,080.00 increase over the search fee and supplemental search fee that was in effect prior to November of 2007.

The PCT does not preclude United States applicants from filing patent applications directly in the patent offices of those countries which are Contracting States of the PCT (with or without previously having filed a regular national application under 35 U.S.C. 111(a) or 111(b) in the United States) and taking advantage of the priority rights and other advantages provided under the Paris Convention and the World Trade Organization (WTO) administered Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement). *See* MPEP § 1801. That is, the PCT is not the exclusive mechanism for seeking patent protection in foreign countries, but is instead simply an optional alternative route available to United States patent applicants for seeking patent protection in those countries that are Contracting States of the PCT. *See id.*

In addition, an applicant filing an international application under the PCT in the United States Receiving Office (the United States Patent and Trademark Office) is not required to use the United States Patent and Trademark Office as the International Searching Authority. The European Patent Office (except for applications containing business method claims) or the Korean Intellectual Property Office may be selected as the International Searching Authority for PCT international applications filed in the United States Receiving Office. The applicable search fee if the European Patent Office is selected as the International Searching Authority European is currently $2665.00 (set by the European Patent Office), and the applicable search fee if the Korean Intellectual Property Office is selected as the International Searching Authority is currently $244.00 (set by the Korean Intellectual Property Office). The Office also recently entered into an agreement with IP Australia under which IP Australia may be selected as the International Searching Authority for certain PCT international applications filed in the United States Receiving Office.

5. Description of Any Significant Alternatives Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

The alternative of not adjusting the PCT transmittal and search fees would have a lesser economic impact on small entities, but would not accomplish the stated objectives of applicable statutes. *See* 35 U.S.C. 41(d) (provides that fees set by the Office recover the estimated average cost to the Office of the processing, services, or materials).

6. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Rules

The Office is the sole agency of the United States Government responsible for administering the provisions of title 35, United States Code, pertaining to the examination of patent applications and granting of patents. Therefore, no other federal, state, or local entity shares jurisdiction over the examination and granting of patents.

The Office previously adjusted the patent fees set by statute to reflect fluctuations in the Consumer Price Index (CPI). *See Revision of Patent Fees for Fiscal Year 2009*, 73 FR 47534 (Aug. 14, 2008), 1334 *Off. Gaz. Pat. Office* 45 (Sept. 2, 2008) (final rule). The Office is also in the process of studying the cost of a number of processes and services covered by the cost-recovery provisions of 35 U.S.C. 41(d)(2) (*e.g.*, reexamination proceeding costs), and the Office will propose adjustments to the fees for these processes and services if appropriate. The changes that would be proposed in any rule makings resulting from this study would also not duplicate, overlap, or conflict with the changes proposed in this notice.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, such overlap cannot be avoided except by treaty harmonizing the patent laws for all countries (such as the Paris Convention for the Protection of Industrial Property, or the PCT).

Nevertheless, the Office believes that there are no other duplicative or overlapping rules.

B. Executive Order 13132 (Federalism)

This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

D. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

E. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

F. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

G. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

H. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

I. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

J. Unfunded Mandates Reform Act of 1995

The changes in this final rule do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

K. National Environmental Policy Act

This rulemaking will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

L. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are inapplicable because this rulemaking does not contain provisions which involve the use of technical standards.

M. Paperwork Reduction Act

The changes in this final rule involve information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this notice has been reviewed and approved by OMB under OMB control number 0651–0021. The Office did not resubmit an information collection package to OMB for its review and approval because the changes in this final rule concern revised fees for existing information collection requirements associated with the information collection under OMB control number 0651–0021. The Office will submit fee revision changes to the inventory of the information collection under OMB control number 0651–0021.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

■ 2. The authority citation for subpart is revised to read as follows:

Authority: Secs. 1.401 to 1.499 also issued under 35 U.S.C. 41 and 351 through 376.

■ 3. Section 1.445 is amended by revising paragraphs (a)(1), (a)(2) and (a)(3) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) * * *

(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14)	$240.00
(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16)	$2,080.00
(3) A supplemental search fee when required, per additional invention	$2,080.00

* * * * *

Dated: October 21, 2008.

Jon W. Dudas,

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

[FR Doc. E8–26711 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2008–0306; FRL–8724–7]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; State of California; PM–10; Revision of Designation; Redesignation of the San Joaquin Valley Air Basin PM–10 Nonattainment Area to Attainment; Approval of PM–10 Maintenance Plan for the San Joaquin Valley Air Basin; Approval of Commitments for the East Kern PM–10 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving the State of California's request under the Clean Air Act (CAA or the Act) to revise the designation for the San Joaquin Valley (SJV) serious nonattainment area for particulate matter of ten microns or less (PM–10) (SJV nonattainment area) by splitting the area into two separate nonattainment areas: The San Joaquin

Valley Air Basin (SJVAB) serious PM–10 nonattainment area and the East Kern serious PM–10 nonattainment area. EPA is also redesignating the SJVAB nonattainment area to attainment for the PM–10 national ambient air quality standard (NAAQS) and approving the PM–10 maintenance plan, motor vehicle emissions budgets and conformity trading mechanism for the area. EPA is also excluding from use in determining that the area has attained the standard exceedances on July 4, 2007, and January 4, 2008, that EPA has concluded were caused by exceptional events. Finally, EPA is approving enforceable commitments by the Kern County Air Pollution Control District and the California Air Resources Board to install a PM–10 monitor in the East Kern nonattainment area and to address CAA requirements under section 189(d) as necessary for the area.

DATE: This rule is effective on December 12, 2008. The motor vehicle emission budgets are applicable as of November 12, 2008.

ADDRESSES: EPA has established docket number EPA-R09–OAR–2008–0306 for this action. The docket is available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, (415) 972–3959, *lo.doris@epa.gov.*

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

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I. Background

On April 25, 2008 (73 FR 22307), EPA proposed the following actions:

- Approval of the State of California's request to revise the designation for the SJV serious PM–10 nonattainment area by splitting the area into two separate nonattainment areas, the SJVAB serious PM–10 nonattainment area and the East Kern serious PM–10 nonattainment area.
- Redesignation of the SJVAB nonattainment area to attainment for the PM–10 NAAQS and approval of the maintenance plan, motor vehicle emissions budgets and conformity trading mechanism for the SJVAB area.
- Exclusion from use in determining that the SJVAB area has attained the standard two exceedances that EPA has concluded were caused by exceptional events that occurred on July 4, 2007, and January 4, 2008.
- Approval of enforceable commitments by the Kern County Air Pollution Control District (KCAPCD) and the California Air Resources Board (CARB) to install a PM–10 monitor in the East Kern nonattainment area and to address CAA requirements under section 189(d) as necessary for the East Kern area.

Subsequently, On May 23, 2008, EPA extended the public comment period for two weeks, until June 10, 2008. 73 FR 30029. EPA issued the extension in order to notify the public of a minor change in the motor vehicle emissions budgets and to provide the public with the opportunity to consider these technical corrections.

Under section 107(d)(3)(D) of the CAA, the Governor of any state may, on the Governor's own motion, submit to EPA a revised designation of any area or portion thereof within the state.[1] EPA is required to approve or deny the revised designation within 18 months of receipt. On January 31, 2008, the State submitted to EPA a revised designation that involves a boundary change only and not a change in status (e.g., from ''nonattainment,'' to ''attainment'' or ''unclassifiable'') of any area.

Section 107(d)(3)(E) of the CAA states that an area can be redesignated to attainment if the following conditions are met:

(1) EPA has determined that the area has attained the NAAQS.

(2) The applicable implementation plan has been fully approved by EPA under section 110(k) of the CAA.

(3) EPA has determined that the improvement in air quality is due to permanent and enforceable reductions in emissions.

(4) The State has met all applicable requirements for the area under section 110 and Part D of the CAA.

(5) EPA has fully approved a maintenance plan, including a contingency plan, for the area under section 175A of the CAA. These requirements are discussed in more detail in a September 4, 1992, EPA memorandum, ''Procedures for Processing Request To Redesignate Areas to Attainment,'' John Calcagni, Director, Air Quality Management Division (Calcagni memorandum).

The proposed rule provides a more detailed discussion of the background pertinent to this final action.

II. Public Comments and EPA Responses

EPA received one letter in support of EPA's proposed actions from the San Joaquin Valley Air Pollution Control District (SJVAPCD or the District) and two letters with adverse comments. As EPA sets forth in detail in its responses to comments below, in taking final action EPA has fully considered all data pertinent for regulatory use in determining attainment in the SJVAB area and EPA continues to believe that the area has attained the PM–10 standard. EPA has also determined that the State's request for redesignation and the maintenance plan for the SJVAB area meet the applicable requirements of the CAA. In addition, EPA is granting the State's request for a boundary revision for the area based on a multiplicity of factors. The available monitoring data for the East Kern area, while limited, also indicate that concentrations are well below the NAAQS. Thus, for the reasons set forth in the responses to comments below, as well as in the proposed rule, EPA is finalizing its proposed determinations as fully meeting the requirements of the CAA.

A. Area Has Attained

Comment 1: Earthjustice (EJ) states that the first condition that a nonattainment area must meet in order to be redesignated to attainment under CAA section 107(d)(3)(E) is that EPA has determined that the area has actually attained the NAAQS. EJ alleges that the SJV nonattainment area has recorded multiple exceedances of the standard during the period that EPA is relying on to demonstrate attainment and that EPA is thus ignoring a serious air quality problem and the health impacts associated with it. EJ incorporates by reference and attaches its previous comments on EPA's attainment determination that claim the problem EPA is ignoring has existed for

[1] Boundary changes are an inherent part of a designation or redesignation of an area under the CAA. *See* CAA section 107(d)(1)(B)(ii).

many years, is part of what led EPA to designate the SJV area nonattainment in the first place and is caused by ongoing human activity that is not reasonably controlled.

Response 1: The previous comments to which EJ refers in its June 10, 2008 comment letter on the proposed rule are contained in its August 18, 2006 comment letter with attachments A–H, October 26, 2007 comment letter, December 29, 2006 Petition for Reconsideration and March 21, 2007 Petition for Withdrawal, with attached declarations from Sarah Jackson and Jan Null. EJ raised the same issues as it raises here during EPA's rulemakings regarding the 2006 determination of attainment for the SJV nonattainment area and 2008 affirmation of that determination. EPA fully responded to EJ's comments at that time. See the final rules at 71 FR 63642 (October 30, 2006) and 73 FR 14687 (March 19, 2008). *See* also the proposed rules for these actions at 71 FR 40952 (July 19, 2006) and 72 FR 49046 (August 27, 2007). As we explained in our responses to EJ's comments in the final rules, EPA believes that the SJV area has attained the PM–10 NAAQS and that the exceedances noted by EJ were properly excluded from consideration under the Agency's Exceptional Events Rule (EER)(72 FR 13560; March 22, 2007).

EJ subsequently filed petitions for review of the October 2006 and March 2008 final rules in the U.S. Court of Appeals for the Ninth Circuit. *Latino Issues Forum, et al.* v. *EPA,* Nos. 06–75831 and 08–71238.[2] In its opening brief in these cases, filed on June 16, 2008, EJ again raises these issues. In its brief in opposition, filed on September 3, 2008, EPA again responds to EJ's arguments. EJ was required to raise any issues regarding the 2006 attainment determination and 2008 affirmation of that determination during those rulemakings and in the Ninth Circuit in *Latino Issues Forum* and cannot relitigate the same issues here.

Moreover, in the proposed rule for today's final action we proposed to exclude under the EER data showing exceedances in the SJV nonattainment area on July 4, 2007 and January 8, 2008, and concluded that the area continued to attain the PM–10 standard through February 2008. We did not receive any adverse comments on this aspect of our proposed rule. In this final action, for the reasons set forth in the proposed rule and in EPA's concurrence letters to which it refers, we are concurring with the State's flagging of those data as caused by fireworks and high wind exceptional events, and excluding those data from consideration in determining that the SJVAB area continues to attain the standard.

Finally, EPA is aware of PM–10 exceedances recorded on May 21, 2008 at the Corcoran and Bakersfield Federal Equivalent Method (FEM) monitors and the Corcoran Federal Reference Method (FRM) monitor, and on May 22, 2008 at the Corcoran FEM. On June 24, 2008, the District posted on its website documentation that these exceedances were caused by a natural event, i.e., high winds. The comment period ended on July 24, 2008 and no public comments were received. The documentation was submitted to EPA on August 12, 2008 and EPA has concurred that these exceedances should be flagged as exceptional events. Letter from Wayne Nastri, EPA to Mary D. Nichols, CARB, September 24, 2008.

EPA is not taking comment on whether the May 2008 exceedances should be excluded from the determination in this final rule that the SJVAB area continues to attain the PM–10 standard. The determination of whether an area has attained the PM–10 standard is based on the most recent three consecutive calendar years of data. As mentioned above and in other EPA actions, the SJVAB area has attained the PM–10 standard based on data for the three-year period from 2003 through 2005 and the three-year period from 2005 through 2007. See 71 FR 63642 and 73 FR 14687. Because 2008 has not ended, EPA cannot determine whether the area has attained the standard based on the three-year period from 2006 through 2008. We can, however, determine with less than three years of data whether the SJVAB area has failed to attain in the period from 2006 to date. *See* 40 CFR part 50, appendix K, section 2.3(c) and 71 FR 63642, footnote 26.

Because the May 21 and 22, 2008 exceedances are the only exceedances at the Corcoran monitors since 2006 not excluded through notice and comment rulemaking from regulatory consideration, the expected number of exceedances recorded at the FRM monitor, based on the May 21 exceedance, is three and the expected number of exceedances recorded at the FEM monitor on May 21 and May 22 is two.[3] Similarly, because the May 21, 2008 exceedance is the only exceedance recorded at the Bakersfield monitor since 2006 not excluded from regulatory consideration through notice and comment rulemaking, the expected number of exceedances at the Bakersfield monitor is one. Thus, even if EPA does not exclude the May 21 and 22, 2008 exceedances from regulatory consideration, the SJVAB area continues to attain the PM–10 NAAQS to date because both Corcoran and Bakersfield have an expected number of exceedances of less than or equal to one per year, averaged over the three year period 2005–2007 and through 2008 to date. All other monitors in the SJV area had an expected number of exceedances of less than or equal to one per year during these periods. EPA thus determines that the SJVAB area has attained the PM–10 NAAQS as required by section 107(d)(3)(E)(i).

B. Fully Approved SIP

Comment 2: EJ states that the second condition for redesignation under section CAA section 107(d)(3)(E) is that an area seeking redesignation must have a fully approved state implementation plan (SIP) and must satisfy all requirements that apply to the area and that the SJV nonattainment area does not have such a SIP. EJ argues that while EPA concedes that it has never approved contingency measures for the area and has instead suspended this requirement under the Agency's Clean Data Policy, neither the policy nor the cases EPA cites addresses PM–10 nonattainment areas and therefore do not square EPA's action with the mandate under CAA section 189(c) that such areas continue to achieve the milestones for emission reductions in order to demonstrate reasonable further progress (RFP) ''until the area is redesignated to attainment.'' EJ believes that because contingency measures are also necessary to ensure this progress is achieved, EPA cannot suspend the requirement for these measures. Citing *Engine Mfrs. Ass'n* v. *EPA,* 88 F.3d 1075, 1089 (D.C. Cir. 1996), EJ asserts that EPA does not have the authority to waive statutory requirements and circumvent redesignation provisions because it believes compliance with those requirements is unnecessary.

Response 2: In 2006 EPA approved the entire nonattainment plan for the SJV area,[4] including the CAA section 189(c)(1) reasonable further progress milestones, except for the CAA section 172(c)(9) contingency measures, on

[2] The Ninth Circuit has consolidated the two petitions for review.

[3] Note that the Corcoran FRM operates on a one-in-three day schedule and that EPA does not combine PM–10 data collected with different monitoring methods, i.e., FRMs and FEMs. See Memorandum from Gerald A. Emison, EPA, to EPA Regional Division Directors, ''Revision to Policy on the Use of PM–10 Measurement Data,'' November 21, 1988 at 3.

[4] ''2003 PM10 Plan, San Joaquin Valley Plan to Attain Federal Standards for Particulate Matter 10 Microns and Smaller'' (2003 PM–10 Plan).

which EPA deferred action. 69 FR 30006 (May 26, 2004). EPA subsequently determined that the contingency measures requirement for the SJV area was suspended as a result of its October 2006 determination that the area has attained the PM–10 standard. 71 FR 63642, 63663. During that rulemaking, EJ raised the same issues with regard to EPA's Clean Data Policy [5] and statutory construction as it raises here. EPA responded to EJ's arguments in the final rule. *See id.* at 63643–63647. EJ again raises these issues in its opening brief in *Latino Issues Forum.* EPA again responds to EJ's arguments in its brief in opposition. EJ was required to raise any issues regarding the suspension of the contingency measures requirement during EPA's 2006 attainment determination rulemaking and in *Latino Issues Forum.* EJ did so and cannot relitigate the same issues here. Because EPA has approved SIP provisions submitted by California for the SJVAB area that address all applicable CAA requirements, EPA has concluded that the CAA section 107(d)(3)(E) requirement for a fully approved SIP has been met.

In addition, in the context of evaluating the area's eligibility for redesignation, there is a separate and additional justification for finding that the section 172(c)(9) contingency measures are not an applicable SIP requirement for purposes of redesignation. Prior to and independently of that policy, and specifically in the context of redesignations, EPA interpreted the contingency measure requirement as not applicable for purposes of redesignation. In the General Preamble EPA stated that:

[t]he section 172(c)(9) requirements are directed at ensuring RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans * * * provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas.

See also Calcagni memorandum at 6 (''The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard.''). Thus, even if the contingency measure requirement had not previously been suspended, it would not apply for purposes of evaluating whether an area that has attained the standard qualifies for redesignation. EPA has enunciated and held this position since the General Preamble was published more than sixteen years ago and represents the Agency's interpretation of what constitutes applicable requirements under section 107(d)(3)(E). The Courts have recognized the scope of EPA's authority to interpret ''applicable requirements'' in the redesignation context. See *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004).

C. Improvements in Air Quality Must Be Due to Permanent and Enforceable Emission Reductions

Comment 3: EJ states that a 1992 guidance memorandum from John Calcagni lays out the steps that an area must take to show that the improvement in air quality is attributable to permanent and enforceable reductions in emissions, the third condition for redesignation to attainment under CAA section 107(d)(3)(E). EJ claims that this analysis should include estimating the percentage reductions achieved from the federal and state controls implemented in the area, taking into account permitted emission rates, production capacities and other related information. EJ states that EPA, banking on its waiver of all the violations during the period of interest, neglected to perform the proper analyses in the Calcagni memorandum and merely repeats the District's belief, based on four observations (comments 4 through 7 below), that the area is attaining the standard.

Response 3: As discussed in our proposed rule, the Calcagni memorandum states that the state must be able to reasonably attribute the improvement in air quality to emission reductions which are permanent and enforceable, and the improvement should not be a result of temporary reductions (e.g., economic downturns or shutdowns) or unusually favorable meteorology. The Calcagni memorandum also states that in making this showing the state should estimate the emission reductions from adopted and implemented federal, state and local control measures, and consider the emission rates, production capacities, and other related information to show that the air quality improvements are the result of implemented controls. Our proposed rule discusses how each of these factors is addressed by the State in the ''2007 PM10 Maintenance Plan and Request for Redesignation,'' September 20, 2007, SJVAPCD (2007 Plan). 73 FR 22307; 2008, footnote 8; 22311–22312.

In general, the 2007 Plan shows that there has been a significant improvement in PM–10 air quality since 1990, noting that there were 33 estimated exceedance days during 1990–1992 and 2.9 exceedance days during 2002–2004. This decrease in exceedance days (and emissions) occurred during a period of rapid economic growth in the SJVAB area as indicated by the increases in population and vehicle miles traveled (VMT). The 2007 Plan did not find any evidence of significant shutdowns that would cause the decline in exceedance days. The 2007 Plan analyzed the meteorology in the SJVAB area during 2003–2006 by comparing the average annual wind speeds, precipitation levels and stability levels to long-term averages and found that there was no consistent pattern to show that there was favorable meteorology leading to the improvement in PM–10 levels during 2003–2006.

The 2007 Plan states that over 500 new rules and rule amendments have been adopted, reducing NO_X and PM–10 emissions from a wide range of source categories, and it shows decreases in the overall emissions of NO_X and PM–10 (which include all emissions from area sources as well as from permitted major sources) since 2000. A more detailed discussion of these analyses can be found in our proposed rule and in the 2007 Plan. EPA's analysis is based on the State's assessment and EPA continues to believe that the State has demonstrated that the improvement in PM–10 air quality in the SJVAB area is a result of permanent and enforceable reductions in emissions and has adequately addressed the provisions of the Calcagni memorandum.

Finally, as discussed in the response to comment 1 above, EPA has determined that the SJV area has attained the PM–10 standard. 71 FR 63642; 73 FR 14687. These determinations included EPA's concurrence with the State's and Santa Rosa Rancheria Tribe's conclusion that a number of exceedances were caused

[5] EPA has long interpreted the CAA to provide that certain nonattainment area requirements, the purpose of which are to ensure attainment of the relevant NAAQS by the applicable deadline, will no longer apply once an area has attained that NAAQS, and for as long it continues to do so until it is redesignated to attainment status. While referred to as the Clean Data Policy, it is more accurately described as EPA's interpretations of the relevant provisions of Title I, Part D of the CAA. *See Sierra Club* v. *EPA,* 375 F.3d 537, 541–42 (7th Cir. 2004); *Sierra Club* v. *EPA,* 99 F.3d 1551, 1156–57 (10th Cir. 1996). EPA first set forth this interpretation in its ''General Preamble for the Interpretation of Title I of the Clean Air Act Amendments of 1990,'' (General Preamble) thereafter reiterated it in several policy memoranda and since codified the policy with respect to ozone and PM–2.5 nonattainment areas. 57 FR 13498, 13564 (April 16, 1992), 40 CFR 51.918 (ozone) and 51.1004(c) ($PM_{2.5}$). EPA has applied the policy to numerous PM–10 nonattainment areas, including the SJV area. For an expanded description of the policy and our application of it, see Respondent EPA's Merits Brief in *Latino Issues Forum* at 7–8, 71 FR 40952, 40954 and 71 FR 63642, 63644.

by exceptional events and thus should be excluded from regulatory consideration. *Id.* EJ seems to suggest that EPA's analyses should include these exceedances even though they have been properly excluded from regulatory consideration. EPA disagrees.

Comment 4: EJ claims that the District provides a chart (2007 Plan at 24, Figure 2) showing a downward trend in air pollution levels that is completely misleading because it does not include EPA-acknowledged exceedances in 2004 and 2005, let alone the many exceedances EPA has ignored in its attainment determination.

Response 4: The District's chart (2007 Plan at 24, Figure 2) shows a long-term downward PM–10 trend from 1990 to 2006 for the SJVAB area by plotting the estimated exceedance days over the NAAQS. The estimated exceedance days in this chart are based on exceedances recorded with FRMs and not FEMs such as continuous beta attenuation monitors (BAMs). EPA believes that the District's chart is not misleading and provides a general picture of the long-term trend for PM–10 and that 1990 is a reasonable year to begin the analysis because that was the year the CAA was amended.

EJ's comment letter (page 4) includes a chart, ''PM–10 Trend,'' that appears to revise the 2007 Plan's chart by adding the exceedances from BAMs that occurred in 2004 and 2005 and by removing the data for 1990 in order to show a less precipitous decline in PM–10 levels. However, even with the exclusion of the 1990 data and the addition of the exceedances from the BAMs, EJ's ''PM–10 Trend'' chart still shows a decline in PM–10 levels.

Moreover, the 2007 Plan provides a summary in Table 10 of the declining annual average emissions inventories from 1990 through 2005 which is consistent with the District's trends chart. Table 10 shows PM–10 emissions decreasing by 46 tons per day (tpd) and NO_X emissions decreasing by 228 tpd during this time period.

Finally, as discussed above, EPA has not ignored any recorded exceedances but rather has followed its regulations to exclude from regulatory consideration any exceedances that are caused by exceptional events. 73 FR 14687; response to comment 3 above. EPA also set forth in its 2006 attainment determination its conclusions as to prior monitored data. 71 FR 63642.

Comment 5: EJ claims that while the District asserts that growth in the SJV nonattainment area has been rapid since 1990 but that emissions have decreased, the sources of these claimed reductions do not support redesignation.

Response 5: See responses to comments 1, 3 and 4 above, and 7 and 8 below.

Comment 6: EJ alleges that the District and EPA conclude without justification that the District's meteorological analysis shows that favorable meteorology did not lead to the improvements in air quality. Instead, EJ argues, the analysis shows that from 2004 to 2006, the SJV nonattainment area experienced some of the wettest years on record and that 2003 through 2006 experienced lower than average stability levels, which EPA and the District concede would lead to better dispersion conditions and lower PM–10 levels. As a result, EJ claims the data provided undercut any claim that the alleged air quality improvement is likely to be maintained.

Response 6: Our proposed rule summarizes the meteorological analysis provided in the 2007 Plan which includes an examination of the precipitation, temperature wind speeds and atmospheric stability during the period 2003 through 2006. The summary was based on data presented in Appendix C to the 2007 Plan. As EJ comments, there were some conditions that favored lower PM–10 levels; however, there were also conditions that favored higher PM–10 levels. Conditions that favored higher PM–10 levels included no variation in annual average wind speeds (which are generally quite low for the SJV area), warmer than average temperatures and two dry years ranking 98th and 112th in wetness (with the 1st year being the wettest year) during a 128 year period. Since there were conditions that both favored and did not favor higher PM–10 levels, the conclusion of the 2007 Plan and EPA's analysis is that there was no consistent pattern to show that attainment was a result of unusually favorable meteorology. 73 FR 22307, 22312.

Finally we note that the Calcagni memorandum makes clear that ''[a]ttainment resulting from * * * unusually favorable meteorology would not qualify as an air quality improvement due to permanent and enforceable emission reductions.'' Calcagni memorandum at 4. Therefore EPA disagrees with EJ's comment that the meteorological data indicate that the air quality improvement will not likely be maintained.

In addition, EPA obtained available information on precipitation, average monthly temperatures and wind speeds for 2007 and compared the 2007 data to the averages presented in Appendix C to the 2007 Plan at Tables C–1, C–2 and C–3. (Atmospheric stability data for 2007 was not available.) The total precipitation for 2007 was 7.03 inches (*http://www.wrh.noaa.gov/hnx/fat/normals/fatrnyr.htm*) which is lower than the average precipitation of 10.13 inches for 1878 through 2006 (2007 Plan at Table C–1) and would favor higher PM–10 levels. The average monthly temperatures in degrees Celcius for 2007 were 4.6 for January, 9.5 for February, 14.3 for March, 15.9 for April, 20.7 for May, 24 for June, 26.3 for July, 26.3 for August, 21.7 for September, 16.1 for October, 11.9 for November and 5.5 for December. (*http://www.weather.gov/climate/xmacis.php?wfo=hnx*) When compared to the average monthly temperatures from 1900 through 2005 (2007 Plan at Table C–2), the average temperatures for the months of March, May, June and August were higher in 2007 than average and would favor higher PM–10 levels. Finally, the average wind speed for 2007 was 3.7 miles per hour (mph) (*http://www.cimis.water.ca.gov*) which is consistent with the average wind speed of 3.72 mph for 1984 through 2006 (2007 Plan at Table C–3) and would favor high PM–10 levels. Since the available 2007 meteorological data favor higher PM–10 levels, EPA continues to believe that there is no consistent pattern that would establish that attainment has resulted from unusually favorable meteorology.

Comment 7: EJ disputes EPA's conclusion that improvements in air quality are the result of permanent and enforceable reductions in emissions from rules adopted by the District since 1992. EJ claims that most of these rules were adopted only in the last few years and therefore any trend in emission reductions that can be inferred from the chart provided by the District (2007 Plan at 24, Figure 2) cannot be attributed to these rules. EJ suggests that the drop in exceedance days between 1990 and 1992 might be due to a difference in the methodologies for measuring exceedances for the TSP and PM–10 standards. EJ provides its own chart, ''PM–10 Trend,'' adjusted to include the exceedance days that it says EPA has acknowledged, that purports to show only minimal changes in the recurring pattern of PM–10 violations over the last 15 years.

Response 7: On July 1, 1987, EPA revised the NAAQS for particulate matter by replacing the standards for total suspended particulate matter (TSP) with new standards applying only to PM–10. 52 FR 24672. While PM–10 monitoring data have been collected since 1987 (see 71 FR 63642, 63653), the District and CARB have not reported TSP data to EPA's Air Quality System

(AQS) database since 1989. Therefore any difference in measurement methodologies for the two pollutants could not be the cause of the drop in exceedance days between 1990 and 1992.

Since enactment of the 1990 CAA Amendments, the State has adopted and submitted several PM–10 plans. These include a moderate area plan under CAA section 189(a), a serious area plan under section 189(b) and a serious area plan under section 189(d) (i.e., the 2003 PM–10 Plan approved by EPA in 2004 and discussed above). The 2003 PM–10 Plan provides a summary of the many State, District and EPA rules adopted from 1990 through 2003. See 2003 PM–10 Plan at Tables 4–1, 4–2, 4–3 and 4–4. The 2003 PM–10 Plan also includes commitments for additional PM–10 and NO_X measures, all of which were adopted by the District and State after 2003 and most of which have been approved by EPA. See response to comment 8 below.

The District's chart (2007 Plan, Figure 2) shows that PM–10 levels have declined from 1990 through 2006 while these PM–10 plans and rules have been adopted and implemented. We note that even EJ's own ''PM–10 Trend'' chart shows a general decrease in PM–10 levels since 1992 and since early 2000.

Furthermore, the 2007 Plan shows that significant reductions in PM–10 and NO_X emissions occurred from the year 2000 to the year 2005, the time period during which the SJV area attained the PM–10 standard. NO_X emissions have declined from 673 tpd in 2000 to 606 tpd in 2005 and PM–10 emissions have declined from 324 tpd in 2000 to 284 tpd in 2005. 2007 Plan; Staff Report, Air Resources Board, ''Analysis of the San Joaquin Valley 2007 PM10 Maintenance Plan,'' (ARB Staff Report for 2007 Plan) Appendix B.[6]

As can be seen from the above discussion and our responses to previous comments, PM–10 exceedance days and PM–10 and NO_X emission levels have declined while at the same time the SJV area has exhibited significant growth in population and vehicle miles traveled. 2007 Plan at 24, Figure 2 and at 26, Figures 3 and 4. Thus EPA continues to believe that it is reasonable to attribute the improvement in PM–10 air quality to the emission reductions from adopted rules that are permanent and enforceable.

Comment 8: EJ argues that the District's failure to estimate the tons or percent reduction from the baseline year achieved by its PM–10 control measures makes it difficult to assert that any improvements in air quality are the result of such controls. Further, while EPA claims that the District has adopted all of its rule commitments in the 2003 PM–10 Plan, only 2 of the 14 commitments have received EPA approval according to EJ. The maintenance plan identifies 8 additional rules, only 3 of which have been approved by EPA. EJ states that of the 22 rules the District identified during its PM–10 planning process to help reduce PM–10 in the SJV nonattainment area, only 5 are enforceable elements of the SIP.

Response 8: The 2007 Plan provides a summary of overall NO_X and PM–10 emissions and shows that emissions have decreased from approximately 1177 tpd in 1990 to approximately 1000 tpd in 2000 to approximately 900 tpd in 2005 and estimates that they will continue to decrease to approximately 800 tpd in 2010. 2007 Plan at Table 10 and 73 FR 22307, 22312. These declining emissions levels have occurred as population and VMT have increased and are due to the emissions reductions from rules and control measures that have been adopted and implemented since 1990. 2007 Plan at 26 through 27 and 2003 PM–10 Plan at Tables 4–1, 4–2, 4–3 and 4–9.

The 2003 PM–10 Plan summarizes the numerous rules and control measures adopted by the SJVAPCD, the State and EPA prior to 2003. 2003 PM–10 Plan at Tables 4–1, 4–2 and 4–3. The 2003 PM–10 Plan also includes District commitments to achieve additional reductions. 2003 PM–10 Plan at Table 4–9. As discussed below, the commitments have all been converted to adopted rules. The emissions reductions from all of the 2003 PM–10 Plan's rules, control measures and adopted commitments are reflected in the 2007 Plan's emissions inventory. ARB Staff Report for 2007 Plan at Appendix B.

It is not clear what year EJ considers to be the baseline year; however, the 2007 Plan provides emissions inventories for the years 1990, 2000, 2005 and 2010 which include the estimated tpd of reductions achieved by the PM–10 rules, control measures and rules adopted pursuant to commitments. 2007 Plan at Table 10 and ARB Staff Report for 2007 Plan at Appendix B. Thus, EPA believes that the State and District have estimated the tpd reductions from several baseline years (1990, 2000 and 2005) achieved by its PM–10 control measures and have shown that the improvements in air quality are the result of such controls.

Regarding EJ's comment that only five of the 22 rules the District identified during its PM–10 planning process are enforceable elements of the SIP, EPA notes that this information was updated in the 2007 Plan. See ''Errata, 2007 PM10 Maintenance Plan and Request for Redesignation,'' October 9, 2007, included in the 2007 Plan submittal to EPA. Table 1 below summarizes the EPA-approved rules from the 2003 PM–10 Plan commitments and provides the EPA approval dates for these rules as applicable. EPA has approved all but three of the submitted rules (Rules 4694, 4401 and 9510).

TABLE 1—SUMMARY OF EPA ACTIONS ON 2003 PM–10 PLAN COMMITMENTS

2003 PM–10 plan commitment[7] (pollutants covered by commitment)	Adopted rule number and title	EPA action
A. Agriculture (Conservation Management Practice Program) (PM–10, VOC).	4550—Conservation Management Practices ...	Approved 2/14/06, 71 FR 7683.
B. Cotton Gins (PM–10)	4204—Cotton Gins	Approved 11/9/06, 71 FR 65740.
C. Dryers (NO_X)	4309—Dryers, Dehydrators, and Ovens	Approved 5/30/07, 72 FR 29886.
D. Fugitive PM–10 (Regulation VIII) (PM–10) ..	8011—General Requirements	Approved 2/17/06, 71 FR 8461.
	8021—Construction, Demo, Excavation	
	8031—Bulk Materials.	
	8041—Carryout and Trackout.	
	8051—Open Areas.	
	8061—Paved and Unpaved Roads.	
	8071—Unpaved Vehicle/Equip Traffic Areas.	

[6] See footnote 2 of the proposed rule. 73 FR 22307, 22308.

TABLE 1—SUMMARY OF EPA ACTIONS ON 2003 PM–10 PLAN COMMITMENTS—Continued

2003 PM–10 plan commitment [7] (pollutants covered by commitment)	Adopted rule number and title	EPA action
	8081—Agricultural Sources.	
E. Glass-Melting Furnaces (SO_X)	4354—Glass Melting Furnaces	Approved 8/1/07, 72 FR 41894.
F. Gas-Fired Oilfield Steam Generators (SO_X)	4406—Sulfur Compounds From Oilfield Steam Generators—Kern County.	Not adopted by District.
G. Indirect Source Review, and Indirect Source Mitigation Fee (NO_X, PM–10).	9510—Indirect Source Review	Under EPA Review.
H. Solid Fuel Boilers, Steam Generators, and Process Heaters (NO_X, SO_X).	4352—Solid Fuel Fired Boilers, Steam Generators, and Process Heaters.	Approved 5/30/07, 72 FR 29886.
I. Small Boilers, Steam Generators, and Process Heaters (NO_X, SO_X).	4307—Boilers, Steam Generators, and Process Heaters 2.0 to 5.0 mmBtu.	Approved 5/30/07, 72 FR 29886.
J. Water Heaters (Industrial, Commercial, and Institutional) (NO_X).	4308—Boilers, Steam Generators, and Process Heaters 0.075 to 2.0 mmBtu.	Approved 5/30/07, 72 FR 29886.
K. Wineries (VOC)	4694—Wineries	Under EPA Review.
L. Steam Enhanced Crude Oil Production Well Vents (VOC).	4401—Steam Enhanced Crude Oil Production Well Vents.	Under EPA Review.
M. Residential Space Heating (NO_X)	4905—Natural Gas Fired, Fan-type, Residential Central Furnaces.	Approved 5/30/07, 72 FR 29886.
N. Agricultural Internal Combustion Engines (PM–10, NO_X).	4702—Internal Combustion Engines Phase 2	Approved 1/10/08, 73 FR 1819.
Residential Wood Combustion [8]	4901—Residential Wood Burning	Approved 9/30/03, 68 FR 56181.

[7] On May 26, 2004, EPA approved the 2003 PM–10 Plan including commitments for new District rules. See 2003 PM–10 Plan, Table 4–9 List of New District Commitments. The commitments for PM–10 and NO_X reductions were approved as meeting BACM and the commitments for other pollutants (SO_X, VOC) were approved as SIP strengthenings. See 69 FR 30006, 30035 and 69 FR 5412, 5423. The District subsequently amended the 2003 PM–10 Plan and revised Chapter 4 Control Strategy in May 2005; however, the amendments were not submitted to EPA. The EPA-approved commitments are those found in the version of the 2003 PM–10 Plan adopted by the District on December 18, 2003.

[8] In its comment letter, EJ lists Residential Wood Combustion as a commitment from the 2003 PM–10 Plan; however, it was an adopted measure and not a commitment. We have included it in our Table for completeness in addressing EJ's comments.

In addition to the rules in Table 1, the 2007 Plan cites reductions from additional rules that were not included in the 2003 PM–10 Plan's commitments. All of these additional rules have been adopted and submitted to EPA by the State and most have been approved by EPA. Table 2 below provides a summary of EPA actions on these additional rules based on the ''Errata, 2007 PM–10 Maintenance Plan and Request for Redesignation.''

TABLE 2—SUMMARY OF EPA ACTION ON ADDITIONAL RULES IDENTIFIED BY 2007 PLAN

Rule #	Rule title	EPA action
4103	Open Burning (VOC & NO_X)	Approved 4/11/06, 71 FR 18216.
4305	Boilers, Steam Generators, and Process Heaters (NO_X)	Approved 5/18/04, 69 FR 28061.
4409	Components Serving Light Crude Oil or Gases at Production Facilities (VOC)	Approved 3/23/06, 71 FR 14652.
4451 & 4452	Components at Petroleum Refineries (VOC).	
4570	Confined Animal Feeding Operations (VOC)	Under EPA Review.
4604	Can and Coil Coating Operations (VOC)	Approved 5/19/06, 70 FR 28826.
9310	School Bus Fleets (NO_X)	Under EPA Review.

Thus, contrary to EJ's comment, most of the rules identified in the 2007 Plan have been approved by EPA as federally enforceable elements of the SIP. EPA is continuing to process the remainder of the State's submitted rules.

Comment 9: EJ concludes that because the air quality improvements are premised on ignoring multiple violations of the PM–10 standard and fewer than one quarter of the rules the District relies on for reductions are an enforceable part of the SIP, EPA cannot reasonably attribute air quality improvements to permanent and enforceable emission reductions.

Response 9: See above responses to comments 1, 3, 4, 6, 7 and 8.

D. Area Has Met All Applicable CAA Section 110 and Part D Requirements

Comment 10: EJ asserts that the District fails to comply with CAA section 107(d)(3)(E) because it has not met all applicable requirements under section 110 and part D. EJ says that in addition to the contingency measure requirement, the District has not met the section 189(b)(1)(B) BACM requirement because BACM were required to be implemented by January 8, 1993 and EPA has still not approved most of the PM–10 rules relied on (as a result of the 2003 PM–10 Plan commitments) as being BACM-level controls.

Response 10: As noted above, in its October 30, 2006 attainment determination EPA suspended the 172(c)(9) contingency measure requirement and as a result it is no longer an applicable part D requirement. 71 FR 63642, 63663; 73 FR 22307, 22313. In any event, as set forth above (see response to comment 2), independent of its suspension, the contingency measure requirement is not an applicable requirement for purposes of redesignation.

With respect to the section 189(b)(1)(B) BACM requirement, as

discussed in our proposed rule, EPA determined that this requirement was met for the SJV nonattainment area in our approval of the 2003 PM–10 Plan. See 69 FR 30006, 30035. (''EPA is approving the RACM/BACM demonstration for all significant PM–10 and NO_X sources in the SJV as meeting the requirements of sections 189(a)(1)(C) and 189(b)(1)(B)''). In the 2003 PM–10 Plan the District addressed the BACM requirement by providing enforceable commitments to implement BACM rules in the future rather than already adopted rules. During the rulemaking on the 2003 PM–10 Plan, EJ argued that until the relevant BACM requirements are adopted and no longer subject to change in the rule development process for each of these source categories, EPA could not conclusively determine that the plan provides for the implementation of BACM/BACT for all significant sources of PM–10 and PM–10 precursors. In rejecting that argument we stated that:

> [s]ection 189(b)(1)(B) requires that serious area PM–10 plans include '[p]rovisions to assure that the best available control measures for the control of PM–10 shall be implemented no later than 4 years after the date the area is classified (or reclassified) as a Serious Area.' Nothing in this language either requires a state to have adopted controls in place before a SIP revision can be approved into its PM–10 plan or forbids the adoption of an enforceable commitment to meet the statute's BACM [footnote omitted] requirement.

Id. at 30013. We further stated, in fully approving commitments as meeting the Act's BACM requirement that:

> [c]onsistent with this statutory language, EPA has historically determined that an enforceable commitment to adopt and implement BACM in a SIP meets this statutory requirement since it constitutes a 'provision to assure that BACM is implemented' by a fixed deadline. As a result, the commenters' complaint that '[b]y definition the plan fails to implement BACM/BACT for all source categories for which no developed control measures exist' has no merit since the statute itself does not impose such a requirement. Because the statute does not define what is a 'provision to assure BACM is implemented,' EPA may adopt an interpretation reasonably accommodated to the purpose of the statutory provision. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. at 842–44.*

Id. at 30013–30014. In conclusion we stated that:

> In accepting enforceable commitments to meet the requirements of section 189(b)(1)(B), however, EPA has required states to undertake an analysis to ensure that the regulation ultimately adopted pursuant to the commitment will represent a BACM level of control. As we describe in our proposed rule, a state must determine the technical and economic feasibility of potential control measures for each of the significant source categories. 69 FR 5412, 5418. Thus the measure that is the subject of a commitment must describe generally the type and level of control to be adopted.
>
> Moreover, once the ultimate control measure is adopted and submitted to EPA, the Agency undertakes an additional evaluation to ensure that that measure meets the statute's BACM requirements. See, e.g., the Arizona rulemakings in which EPA initially approved as RACM [footnote omitted] a requirement in a state statute to adopt and implement best management practices for agricultural operations and subsequently determined that the rules adopted pursuant to the statute represented RACM/BACM. 64 FR 34726 (June 29, 1999); 66 FR 51869 (October 11, 2001); 67 FR 48718 (July 25, 2002).

Id. at 30014. EPA's interpretation and its full SIP approval of the BACM requirement was not challenged. EPA may rely on prior SIP approvals in approving a redesignation request. Calcagni memorandum at 3; *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d. 984. 989–990 (6th Cir. 1998); and *Wall* v. *EPA,* 265 F.3d 526 (6th Cir. 2001). Finally we note that EPA has approved many of the rules submitted by the State as meeting a BACM level of control. See the Federal Register notices listed in Tables 1 and 2 above in which we approve SJVAPCD PM–10 and NO_X rules.

Comment 11: EJ also claims that the District has failed to submit to EPA a demonstration that the quantitative milestones as required by CAA section 189(c)(1) and (c)(2) and the section 189(d) 5 percent requirement have been met. EJ also claims that the District has not met its commitment to update and improve the 2003 PM–10 Plan by March 2006.

Response 11: CAA section 107(d)(3)(E)(v) requires that a state seeking redesignation of an area to attainment must have met all requirements applicable to the area under section 110 and part D. In interpreting this requirement EPA has stated that ''any requirements that came due prior to submittal of the redesignation request must be fully approved into the plan at or before the time EPA redesignates the area.'' Calcagni memorandum at 5. *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). EPA has approved the 2003 PM–10 Plan's RFP demonstration as meeting the requirements of 172(c)(2) and 189(c)(1) and has approved the plan as meeting the quantitative milestones requirement in section 189(c)(1). 69 FR 30006, 30034. Also, as we explained in our 2006 attainment finding, we believe that once an area attains the NAAQS the requirements of section 189(c)(2) with respect to milestones no longer applies under the Agency's Clean Data Policy. 71 FR 63642, 63646–63647. We also explained in that rulemaking the application of the Clean Data Policy to PM–10. See 71 FR 40952, 40954–40955 and 71 FR 63642, 63643–63645. Apart from the Clean Data Policy, for an area that has attained the standard and is eligible for redesignation, the requirements for milestone demonstrations under section 189(c) have no further meaning or function. Therefore the District was not required to submit milestone demonstrations pursuant to section 189(c).

In addition, EPA approved a commitment in the 2003 PM–10 Plan by the State to submit a SIP revision by March 31, 2006 based on a mid-course review to determine whether the level of emission reductions in the plan is sufficient to attain the PM–10 standards. 69 FR 30006, 30035. EPA approved this commitment as part of the Plan's attainment demonstration. See 69 FR 5412, 5429. While the SJVAPCD adopted a mid-course review SIP addressing the quantitative milestone reporting requirement and mid-course review SIP commitment and submitted the SIP to the State, the State has not submitted the mid-course review SIP to EPA. Nevertheless, EPA's full approval of the attainment demonstration in the 2003 PM–10 Plan fully satisfies the requirement of CAA section 107(d)(3)(E)(v).

Moreover, EPA has determined that the SJV area attained the PM–10 standard in 2005, and continues to attain the standard. The mid-course review requirement is not a requirement under section 110 or Part D, and therefore is not an applicable CAA requirement for purposes of redesignation. Furthermore, even if it were, the requirement for a mid-course review was approved as part of the attainment demonstration. Therefore, because EPA has determined that the SJV area is attaining the PM–10 standard, a submission under the mid-course review provision would not be required for purposes of redesignation. 57 FR 13498, 13564; Clean Data Policy.

Comment 12: EJ claims that EPA misinterprets an October 14, 1994 memorandum from Mary Nichols, EPA, entitled ''Part D NSR Requirements for Areas Requesting Redesignation to Attainment'' as allowing the District to replace its new source review (NSR) program with a prevention of significant deterioration (PSD) program. EJ quotes the memorandum as saying that ''the part D program may be replaced by the corollary PSD program, if it is shown

through the maintenance demonstration that the area will maintain without part D NSR.'' EJ asserts that here neither EPA nor the District has made any such demonstration and claims that this is especially worrisome in light of EPA's recent proposed approval of revisions to the District's NSR program exempting ''so-called minor agricultural sources such as industrial dairy operations.''

Response 12: First, the commenter overlooks the fact, enunciated in our proposed rule, that EPA has previously fully approved the NSR program for the SJV area. We also noted that EPA has recently proposed approval of some revisions to the NSR rule. 73 FR 22307, 22313. EJ's citation to the October 14, 1994 memorandum from Mary Nichols, EPA, entitled ''Part D NSR Requirements for Areas Requesting Redesignation to Attainment'' (Nichols memorandum) is misdirected. The Nichols memorandum's discussion of the need to demonstrate maintenance without fully approved NSR addressed the situation, not the case here, where an area's NSR rule has not been approved. Moreover, as our proposed rule explained, even though EPA previously approved the NSR rule, such approval is not a prerequisite to finalizing our approval of the State's redesignation request. Id. If an area does not have a fully approved NSR program, it can still be redesignated if it shows maintenance without NSR in effect. The 2003 PM–10 Plan and 2007 Plan do not rely on reductions from the area's NSR program. Nothing in the plans' inventories or estimated emissions reductions indicates any reliance on NSR program reductions. Thus, the SJVAB area will maintain the NAAQS without NSR. This is consistent with the provisions of the Nichols memorandum. Finally, we note that while the PSD requirements will apply once the area has been redesignated to attainment, the District's SIP-approved NSR rule will continue to apply with respect to PM–10 until EPA approves a revised NSR rule.

E. Maintenance Plan

Comment 13: EJ maintains that even if all of the other issues it has raised with respect to the redesignation were remedied, EPA cannot approve the redesignation request because the maintenance plan is flawed and cannot be approved. EJ concludes that EPA's decision to approve the maintenance plan without the requisite analysis and without meeting the basic requirements laid out in the Calcagni memorandum leaves little for EJ to comment upon and, as such, is the very definition of arbitrary and capricious. EJ believes that EPA's obligation is to provide not just its legal conclusions but the facts and rationale that support them.

Response 13: EPA disagrees. Our proposed rule lays out all of the requirements for maintenance plans found under the CAA and the Calcagni memorandum and sets forth the Agency's analysis of how the 2007 Plan meets each of those requirements. 73 FR 22307, 22313–22315. In addition, the 2007 Plan itself addresses in detail the requirements in the Calcagni memorandum. Thus EJ's contention that EPA's discussion of the maintenance plan left them ''very little'' to comment on is without basis.

Comment 14: EJ asserts that the 2005 emissions inventory is insufficient to identify the level of emissions in the area because the continuing PM–10 problem is the result of direct PM–10 emissions during the fall rather than secondary wintertime NO_X emissions and the direct PM–10 inventory is expected to increase over the next 10 years. EJ states that EPA's claim that increasing direct PM–10 emissions are offset by a larger decrease in the NO_X inventory demonstrates a lack of understanding of the PM–10 problem in the SJV nonattainment area because reducing secondarily formed PM–10 does nothing to reduce the ongoing direct PM–10 problems. EJ concludes that since the maintenance demonstration is based on an inventory that is insufficient to attain the NAAQS, EPA cannot find that the plan will maintain healthful air for 10 years following redesignation.

In a footnote to its comment above regarding the emissions inventory for the maintenance plan, EJ claims that prior to 2004 the District had never asked EPA to waive PM–10 data but in the past 4 years it has been asked to waive 11 separate events, 10 of them after the Agency's original attainment finding. EJ states that if windy days are this common EPA and the District must accept that the SJV nonattainment area has a windblown dust problem and they must do more to control it. EJ states that an event is only exceptional if it is not expected to recur on a regular basis.

Response 14: As discussed in our proposed rule, the Calcagni memorandum provides that a state should provide an attainment emissions inventory to identify the level of emissions in the area sufficient to attain the NAAQS and, where the state as here has made an adequate demonstration that air quality has improved as a result of the SIP (see above responses to comments 3 through 4 and 6 through 8), the attainment inventory will generally be an inventory of actual emissions at the time the area attained.

The 2007 Plan does exactly what the Calcagni memorandum recommends and selects the 2005 PM–10 and NO_X inventories as the attainment emission inventories because the SJV area attained the standard in 2005. 73 FR 22307, 22314 and 71 FR 63642. The SJV area relies on reductions of both NO_X (a PM–10 precursor) and directly emitted PM–10 sources to achieve attainment. 2003 PM–10 Plan at ES–9 through ES–10, Chapters 2, 4 and 5; 69 FR 5412, 5414 and 69 FR 30006, 30007. Analysis of ambient air quality data for the SJV area shows that it experiences the most frequent and severe exceedances from October through January during stagnant weather conditions (*i.e.*, low wind speeds that are unable to disperse the PM–10).[9] Both direct PM–10 and secondary PM–10 (formed by reactions with NO_X) occur during this time. October and November exceedances are dominated by direct PM–10 emissions and December and January are dominated by secondary PM–10 such as ammonium nitrate (formed when NO_X reacts with ammonia and other components); however, the reduction of both direct PM–10 and NO_X is necessary for reducing ambient PM–10 levels throughout the year. 2003 PM–10 Plan at ES–9 through ES–10 and 5–6 through 5–7. Thus, EPA's belief that the slight increase in PM–10 emissions of 284 tpd in 2005 to 290 tpd in 2020 is insignificant when compared to the substantial NO_X decreases of 606 tpd in 2005 to 328 tpd in 2020 is based on an understanding that high PM–10 levels in the SJV area are caused by both direct PM–10 and precursor NO_X emissions. In addition, consistent with the Calcagni memorandum, the modeled maintenance demonstration is primarily based on modeling similar to the modeling used for the 2003 PM–10 Plan. 73 FR 22307, 22314. Finally, contrary to EJ's comments, there is no ongoing direct PM–10 problem in the SJVAB as we have determined that the area has attained the PM–10 standard. 71 FR 63642 and 73 FR 14687. See also response to comment 1.

EJ's comment in footnote 3 of its letter does not appear to be related to the inventory or any other provision of the maintenance plan in the 2007 Plan or the maintenance plan requirement of CAA section 107(d)(3)(E)(iv). Rather it appears to be an expansion of EJ's argument that the SJV area has not in fact attained the PM–10 standard. In this

[9] As discussed in our attainment affirmation and proposed rule, unusually high winds can also cause exceedances. 73 FR 14687 and 73 FR 22307, 22311.

regard, see response to comment 1 above. Notwithstanding , EPA notes that not all of the exceptional event days in the past five years in the SJV area have been due to high winds. Of the eleven exceptional event days, seven were caused by high wind events and the remaining four by construction, improper monitor siting and fireworks.

Comment 15: EJ states that it is not clear whether the modeling takes into account the September 2004 and November 2005 exceedances EPA has conceded but if it does not then the modeling for the maintenance plan is flawed because it fails to include these higher values in its projections.

Response 15: As discussed in our proposed rule, a state may generally demonstrate maintenance of the NAAQS by either showing that future emissions of a pollutant or its precursors will not exceed the level of the attainment inventory, or by modeling to show that the future anticipated mix of sources and emission rates will not cause a violation of the NAAQS. 73 FR 22307, 22314–22315. See also Calcagni memorandum at 9 and *Wall* v. *EPA*, 265 F.3d 426 (6th Cir. 2001). While only required to use one of these methods, the SJVAPCD showed both with emissions inventory and modeling that the area would maintain the standard for at least ten years after redesignation, in accordance with section 175A. For areas such as the SJV that used modeling for their attainment demonstrations, the same level of modeling should be used for the maintenance demonstrations. The 2007 Plan uses Chemical Mass Balance (CMB) and rollback to demonstrate maintenance of the 24-hour PM–10 standard until 2020 which is consistent with the modeling performed for the 2003 PM–10 Plan. 73 FR 22307, 22314; 2007 Plan at 6–11. The modeling involves selecting a representative day for each location, determining the speciation data for the site based on analysis of the monitoring filters and sources in the area and determining the emissions reductions that are necessary or that will be achieved due to emissions reductions from implemented rules.

The 2007 Plan's maintenance demonstration modeling was based on the highest episodes during the most recent attainment year at the time, 2006. The District selected representative peak winter days for each of the monitors in the SJVAB for modeling, and used the observed values from those days as the basis of its modeling exercise. In addition, fall episode days were included for several monitors. Table 2 of the 2007 Plan summarizes the episode values and the 2020 projections.

One of the objectives in determining appropriate representative episodes is to choose those days that are approximately as severe as the design value for the modeled pollutant. The design value is based on three years of monitoring data, or in this case, 2004 through 2006, and depends on the frequency and completeness of recorded values. In addition, for PM–10, the design values are generally based on FRM data, but FEM data can also be used; however, as noted in footnote 3 above, data from different monitoring instruments are not combined.

The representative days selected for modeling are consistent with the design values for the Corcoran and Bakersfield sites where the September 2004 and November 2005 values were measured. For the Corcoran FRM, the design value is 140 μg/m^3, based on a calculation that includes and explicitly accounts for the 217 μg/m^3 measured in September 2004.[10] This value is very close to, and supports the selection of, the two representative high episode values in the 2007 Plan for Corcoran: A 136 μg/m^3 for the winter episode and a 137 μg/m^3 for the fall episode. The small differences between the design value of 140 μg/m^3 and the selected winter and fall episode values is not an issue because the projected maintenance levels are well below the 24-hour PM–10 standard of 150 μg/m^3. 2007 Plan at Table 2. The Bakersfield FEM does not have a complete set of data from 2004 through 2006, and therefore a design value for this time period cannot be calculated based on the FEM data. However, the 2004–2006 PM–10 design value for Bakersfield using the data collected with the FRM monitor would be 154 ug/m^3.[11] This concentration is consistent with the values of 153 ug/m^3 and 154 μg/m^3 measured during the representative modeled episodes included in the 2007 Plan for Bakersfield. Therefore, the September 2004 and November 2005 exceedances to which EJ refers in its comment were taken into account in the 2007 Plan's maintenance demonstration modeling.

Comment 16: While EJ is glad that the District plans to continue operation of its PM–10 monitoring network, EJ is troubled that the District suggests in its 2008 ''Ambient Air Monitoring Network Plan'' that it may reduce the frequency of its monitoring. EJ hopes that the District will strengthen its network because EJ continues to believe that the current network does not adequately represent the west side communities and the near-highway areas of high concentration and that more monitoring is required.

Response 16: In 2003, EPA evaluated the adequacy of the monitoring network for the SJV area and concluded that it meets all the applicable statutory and regulatory requirements. *See* 69 FR 30006, 30033 and ''Evaluation of the Adequacy of the Monitoring Network for the San Joaquin Valley, California for the Annual and 24–Hour PM–10 Standards,'' Bob Pallarino, EPA, September 22, 2003. We reaffirmed the adequacy of the network in our 2006 determination of attainment for the SJV area. 71 FR 63642, 63648–63658.

With regard specifically to monitoring frequency, EPA regulations require minimum frequencies for manual PM–10 and PM–2.5 samplers at designated state or local air monitoring stations (SLAMS) sites. *See* 40 CFR 58.12. On October 17, 2006 EPA revised its monitoring regulations to require air monitoring agencies to perform an assessment of their monitoring networks every five years according to guidance issued by EPA. *See* 71 FR 61299 and 40 CFR 58.10(d). The first monitoring network assessment required by this regulation must be submitted to EPA by July 1, 2010. Agencies are directed to make changes to their monitoring networks based in part on the results of these network assessments. Such an assessment in the SJVAB area may result in a requirement that the District increase the sampling frequency of certain PM–10 monitors sited to record the maximum concentrations of PM–10 pollution. *See* 40 CFR 58.12(e).

Most manual PM–10 samplers in the SJV monitoring network currently operate at the minimum required frequency of once every six days, except for Corcoran which operates manual PM–10 samplers once every three days. The District has exceeded this required sampling frequency by operating continuous FEM monitors, which produce a 24-hour average PM–10 concentration every day, at three locations in the SJVAB area, Tracy, Corcoran and Bakersfield. According to the District's 2008 ''Ambient Air

[10] If we assume that the September 2004 exceedance is not flagged, the highest recorded PM–10 values from 2004 through 2006 are: (1) 217 μg/m^3 on September 3, 2004; (2) 140 μg/m^3 on October 26, 2006; and (3) 139 μg/m^3 on October 15, 2004. Since the Corcoran FRM operates on a one-in-three day schedule, the design value is based on the second highest recorded PM–10 value, or 140 μg/m^3.

[11] The design value for Bakersfield is calculated using the FRM data set from 2004–2006. The design value in this case would be the highest non-flagged value for the three year period, 154 μg/m^3 measured on December 7, 2006.

Monitoring Network Plan,'' the Corcoran and Bakersfield-Golden State Highway sites are two of the four PM–10 monitoring sites located to record the highest PM–10 concentrations in the SJVAB area.[12] Therefore, the District has already proactively increased the sampling frequency at two high concentration sites to the maximum frequency possible.

Comment 17: EJ believes that the contingency measure provision in the maintenance plan is much too weak and cannot be approved. EJ states that the provision relies first and foremost on trying to excuse any future violation under the EER and then, in the event of any post-redesignation violations, on seeing if there are any estimated reductions achieved that were not counted towards the attainment demonstration that can be used to ''cover'' the violation. EJ does not believe this approach makes sense because if an area is violating the standard, there are no ''extra'' reductions because all of the reductions are by definition not working. EJ believes that while EPA may accept this gaming in the context of RFP demonstrations such an approach would be illegal and arbitrary when real ambient violations are being monitored. EJ believes that the District should adopt the approach suggested in the Calcagni memorandum which sets indicators that trigger contingency provisions before a violation occurs which would avoid NAAQS violations and not just come up with on-paper ''covers'' for those violations.

Response 17: Under CAA section 175A(d), maintenance plans must contain ''such contingency provisions as the Administrator deems necessary to assure that the State will promptly correct any violation of the standard.'' The Calcagni memorandum states that ''EPA will review what constitutes a contingency plan on a case-by-case basis. At a minimum, it must require that the State will implement all measures contained in the Part D nonattainment plan for the area prior to redesignation. * * *'' Calcagni memorandum at 12–13. The memorandum also makes clear that a monitored violation of the standard is appropriate to serve as the indicator or trigger for contingency measures. *Id.* at 12.

EJ's statement that the contingency provisions of the 2007 Plan ''relies first and foremost'' on trying to excuse any future violation under the EER is misleading. The 2007 Plan selects an action level or trigger based on an exceedance of the PM–10 NAAQS of 155 micrograms per cubic meter (μg/m^3).[13] 2007 Plan at 16. In addition, the District may also consider other factors such as a succession of values just below but near the level of the PM–10 standard. In our proposed rule we explained why we believe that an exceedance of 155 μg/m^3 is an appropriate trigger:

> The SJVAB has several continuous PM–10 monitors, and a single measurement of 155 μg/m^3 at one of these monitors would not constitute a violation of the PM–10 NAAQS. Even if a measurement of 155 μg/m^3 is recorded at a one-in-six day FEM, a violation is not necessarily being recorded as the State might need to evaluate the possibility that the measurement is due to an exceptional event.

73 FR 22307, 22315. Thus the contingency plan makes clear that determining whether an exceedance of the PM–10 standard is due to an exceptional event is part of determining whether a violation of the standard actually occurred, which would require corrective actions. In other words, we concluded that the 2007 Plan's action level or trigger, including the exclusion of exceedances caused by exceptional events, meets the statutory mandate that the contingency provisions ''correct any violation of the standard.'' Because it is clearly part of the action level or trigger, and not the corrective actions to be undertaken in the event of a violation, it is not accurate to conclude, as EJ does, that the contingency plan relies ''first and foremost'' on the use of the EER. Moreover, since an exceedance, which is not necessarily a violation, triggers the contingency measure provision, the provision may also be used to prevent violations of the NAAQS, and at a minimum provides for a violation that is determined not to be due to an exceptional event to trigger a measure.

Once the contingency plan is triggered, the District would determine the possible causes of the exceedance and determine if emissions reductions from adopted measures that are not needed to maintain the PM–10 NAAQS are available to serve as contingency measures. 2007 Plan at 16. EJ objects to the use of these excess reductions (i.e., those not relied on in the maintenance demonstration) when ambient concentrations are being monitored.

Initially we note that EPA has long approved contingency provisions that rely on reductions from measures that are already in place but are over and above those relied on in the attainment and RFP demonstrations under CAA section 172(c)(9). See, e.g., 62 FR 15844 (April 3, 1997); 62 FR 66279 (December 18, 1997); 66 FR 30811 (June 8, 2001); 66 FR 586 and 66 FR 634 (January 3, 2001). We discussed this interpretation of section 172(c)(9) in our final PM–2.5 implementation rule. See 72 FR 20586, 20642–20643 (April 25, 2007). This interpretation has also been upheld in *LEAN* v. *EPA,* 382 F.3d 575 (5th Cir. 2004), and the court in that case set forth in detail the reasoning for accepting excess reductions from already adopted measures as contingency measures.

In addition to being triggered by a failure to meet RFP, contingency measures under section 172(c)(9) are triggered when EPA determines that an area has failed to attain a NAAQS. Determinations of whether an area has attained a NAAQS (see, e.g., section 188(b)(2); 71 FR 40952) are based on monitored concentrations. Likewise, here, a determination of whether the action level has been reached is based on monitored concentrations. Therefore our interpretation that excess emission reductions can appropriately serve as section 172(c)(9) contingency measures is equally applicable to section 175A(d) contingency measures.

Furthermore, section 172(c)(9) is considerably less flexible than section 175A(d) in that under the former provision contingency measures are required to be fully adopted measures that will take effect without further action by the state, whereas this is not a requirement in order for the maintenance plan to be approved. Moreover, section 175A(d) grants considerably more discretion to EPA in determining whether to accept contingency provisions in maintenance plans (maintenance plans must contain ''such contingency provisions *as the Administrator deems necessary* to assure that the State will promptly correct any violation of the standard.'' (Emphasis added). In addition, the Calcagni memorandum at 12–13 states that a contingency plan under section 175A(d) ''[a]t a minimum must require that the State will implement all measures contained in the Part D nonattainment plan for the area prior to redesignation. * * *'' The 2007 Plan so provides and goes well beyond this minimum threshold.

The U.S. Court of Appeals for the Sixth Circuit addressed the issue of the adequacy of reductions from already

[12] The other two sites are the Fresno-First Street site and the Stockton-Hazelton site.

[13] An exceedance is defined as a daily value that is above the level of the 24-hour standard (150 μg/m^3) after rounding to the nearest 10 μg/m^3 (i.e. values ending in 5 or greater are to be rounded up). Thus, a recorded value of 154 μg/m^3 would not be an exceedance since it would be rounded to 150 μg/m^3 whereas a recorded value of 155 μg/m^3 would be an exceedance since it would be rounded to 160 μg/m^3. See 40 CFR part 50, appendix K, section 1.0.

adopted measures in the context of section 175A(d) contingency measures in a maintenance plan for Cuyahoga County, Ohio. *Greenbaum* v. *EPA,* 370 F.3d 527 (6th Cir. 2004).[14] There EPA had approved section 172(c)(9) contingency measures into the SIP in 1996 as part of the State's moderate area PM–10 nonattainment plan. In approving these measures EPA found that they provided for emission reductions following any prospective determination that the SIP failed to provide for timely attainment of the NAAQS. In 2000, Ohio submitted a redesignation request with a maintenance plan that included as section 175A(d) contingency provisions the already approved section 172(c)(9) contingency measures. Among other things, the petitioners argued that the CAA does not authorize EPA to use other measures outside the maintenance plan to assure correction of a violation. In upholding EPA's approval of the redesignation, the court found that:

> [t]he Administrator has been granted broad discretion by Congress in determining what is 'necessary to assure' prompt correction. The EPA has approved Ohio's maintenance plan, concluding that its contingency measures provide a means to deal with likely violations. We do not believe that this determination is 'arbitrary, capricious, or manifestly contrary to the statute.' *Chevron, 467 U.S. at 844.*

The Sixth Circuit in *Greenbaum* further noted that Congress contemplated that contingency measures need not be sufficient to correct all violations and that EPA and the state could rely on a combination of factors to correct violations. See the extensive discussion of contingency measures in *Greenbaum.*

Here, the 2007 Plan looks first to emission reductions from adopted measures that are not needed to maintain the PM–10 NAAQS to serve as section 175A(d) contingency measures. If these emission reductions prove to be insufficient to correct the violation, the District commits to proceed with identifying control measures from feasibility studies such as those found in its 2007 Ozone Plan and Proposed 2008 PM2.5 Plan [15] (see 2007 Ozone Plan at Table 6–2 and 2008 PM2.5 Plan at Table 6–4) and with prioritizing measures most relevant for reducing PM–10 emissions. 2007 Plan at 16–17. The SJVAPCD has also provided clarification that if additional control measures are necessary, the SJVAPCD will adopt and implement such measures. Letter from Seyed Sadredin, SJVAPCD, to Deborah Jordan, EPA, April 17, 2008. EPA believes that the 2007 Plan's contingency provisions which rely in part on emissions reductions from adopted measures not needed to maintain the PM–10 NAAQS to correct any PM–10 violation are consistent with the Agency's policies and with the statute. As the court in *Greenbaum* observed, Congress has expressly delegated to EPA the authority to determine what contingency measures are necessary. Here, EPA has determined that the contingency measures, which include both the potential for emission reductions from already adopted measures and from measures to be adopted, clearly are sufficient.

Finally, with respect to EJ's preference, suggested in the Calcagni memorandum, that the contingency plan for the SJVAB area set indicators that trigger contingency provisions before a violation occurs, we note again that the memorandum provides that contingency provisions are to be judged on a case by case basis. *See* also *Greenbaum.* With the exception of the minimum requirement mentioned above, the Calcagni memorandum is not prescriptive and allows for considerable latitude as to what constitutes an adequate contingency plan. The Calcagni memorandum itself provides that a violation of the standard is an appropriate trigger for contingency measures. Calcagni memorandum at 12. See also *Greenbaum.* It is a common practice in maintenance plans to provide that a violation will trigger the requirement for a contingency measure to be implemented. Moreover, as pointed out above, under the contingency measure provisions, a monitored exceedance of the standard that does not itself constitute a violation (e.g., at a continuous monitor or a one-in-three day FRM monitor) could trigger a contingency measure prior to a violation occurring.

F. Revision of Boundary Designation

Comment 18: EJ maintains that the portion of the San Joaquin Valley that EPA now proposes to split off was designated as part of the SJV nonattainment area because, as provided in CAA section 107(d)(1)(A), it was part of the geographic area ''that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the national primary or secondary air quality standard for that pollutant.'' EJ states that EPA makes no attempt to explain how circumstances have changed to justify the removal of this portion of the designated nonattainment area. EJ notes that the SJV area includes other high-elevation areas that are located above the inversion layer and that whether a community is above or below the inversion layer is irrelevant because these areas are part of the Valley and part of the same air basin polluted by emissions generated in the Valley.

Response 18: As discussed in our proposed rule, on January 31, 2008 California requested a boundary redesignation splitting the SJV nonattainment area into two separate nonattainment areas, the SJVAB and East Kern. Section 107(d)(3)(D) of the CAA authorizes the State to submit to EPA a revised designation of any area and EPA is required to approve or deny it within 18 months of receipt of a complete State submittal. The type of revised designation that the State of California requested involves a boundary change only and does not involve a change in status (e.g., from ''nonattainment'' to ''attainment'' or ''unclassifiable'') of any area. Our criteria for evaluating the State's request are discussed in our proposed rule.

In general, the State has provided a compelling technical justification for splitting the nonattainment area which includes an evaluation of the differences in jurisdiction, geography, population and degree of urbanization, employment and traffic/commuting patterns, emissions and air quality. 73 FR 22307, 22308–22310. EJ notes that there are other high elevation areas in the SJV nonattainment area; however, the State has not made a request to revise any other boundaries. In addition, as discussed in our proposed rule, the SJVAB and East Kern areas are in separate air basins and do not have the same mix of air pollution sources. *Id.* EPA continues to believe that it should grant the State's request for a revised designation splitting the SJV nonattainment area into two PM–10 nonattainment areas, the SJVAB area and the East Kern area for the reasons set forth in the proposed rule and in this response.

Comment 19: A commenter states that while the proposal to separate the western portion of the KCAPCD is clear and compelling, the commenter is concerned about environmental justice issues for the East Kern area. The commenter states that if the purpose of the separation is to clean-up one area and ignore the other industrialized area with the State prison, then EPA is not following its ethics concerning

[14] As early as 1995, EPA approved a maintenance plan under section 175A that included contingency provisions that relied in part on measures to be implemented prior to any post-redesignation NAAQS violation. See 60 FR 27028, 27029 (May 22, 1995).

[15] The 2008 PM2.5 Plan was adopted by the District on April 30, 2008, approved by the State on May 22, 2008, and submitted to EPA on June 30, 2008.

environmental justice. The commenter states that communities with prisons serve as a target of environmental neglect and should not be abandoned from environmental laws and attainment requirements and should not be forgotten by EPA.

Response 19: EPA's final action to split the SJV nonattainment area into two nonattainment areas does not relax any requirements. EPA is also approving enforceable commitments for the East Kern area that will ensure progress in meeting CAA requirements for the area. These commitments include the installation of a FRM/FEM [16] and submittal of a SIP addressing applicable CAA requirements if the monitor violates the PM–10 standard. 73 FR 22307, 22317. In the meantime, the existing data from the IMPROVE monitor, although not a FRM or FEM, do not indicate an air quality problem in East Kern—rather they show levels that are consistently significantly below the standard. *See id.* at 22310 (''* * * IMPROVE monitor has, since February 2000, consistently measured PM–10 concentrations far below the PM–10 standard.'').

With respect to the commenter's concerns for fair treatment of the inhabitants of East Kern, EPA is taking steps to assure that the East Kern area will not be forgotten by EPA, and no community in that area will be ''abandoned from environmental laws and attainment requirements.'' EPA is committed to meeting the goals of environmental justice and is equally concerned for the populations of both the SJVAB and East Kern areas. There is no basis for concluding that the population of East Kern is exposed to ongoing levels above the standard, and EPA and the State have worked to provide assurances that the area will be required to conduct more comprehensive monitoring and to adopt additional requirements if needed. Thus EPA recognizes the role of environmental justice and is observing its principles.

Comment 20: A commenter disagrees with the proposed rule's statement that the boundary redesignation makes sense because of the difference in chemical composition of PM–10 between the two areas. The commenter believes this is not a valid statement because there are no FRMs or FEMs in the East Kern area. Furthermore, the commenter states that the one IMPROVE monitor in the East Kern area is inadequate and the chemical composition of the SJVAB and East Kern should not be compared until there is an adequate monitoring system in East Kern. In addition, the commenter concludes that a reanalysis of reported data must be performed before considering attainment for the SJVAB.

Response 20: We based our conclusion that the SJVAB and East Kern should be separate nonattainment areas on multiple factors, only one of which relates to the difference in the types of air pollutants in the two areas. *See* 73 FR 22307, 22310. While the commenter is correct that there is no FRM or FEM in the East Kern area, as stated above, the State and the District have committed to install an FRM/FEM in the East Kern area. Pending data from this new monitor, the IMPROVE monitor does provide useful information regarding the composition of PM–10 in the area. *See id.* and Attachments B and C to letter from James N. Goldstene, CARB, to Deborah Jordan, EPA, January 31, 2008. See also response to comment 19. The newly created East Kern area will retain its nonattainment designation until the State can demonstrate, following assessment of data from the new monitor, that all the applicable CAA requirements for redesignation of the East Kern area are met.

EPA does not agree that a reanalysis of the reported data must be performed before considering whether the SJVAB area has attained the PM–10 standard. As noted above, EPA has found that the SJVAB area has an adequate monitoring system on which to base such a determination. *See* 69 FR 30006, 30033, 71 FR 63642, 63648 and ''Evaluation of the Adequacy of the Monitoring Network for the San Joaquin Valley, California for the Annual and 24–Hour PM–10 Standards,'' Bob Pallarino, EPA, September 22, 2003. To demonstrate attainment, an area must show that it meets the standard over a three-year period. The SJVAB area has demonstrated attainment over three separate 3-year periods—2003–2005, 2004–2006, and 2005–2007, and it continues to attain the standard.

G. Miscellaneous Comments

Comment 21: A commenter states that there are several gaps in evaluating the PM–10 data for the SJVAB from 1990 to 2004 and that given the cyclical nature of PM–10 the downward trend should be considered inconclusive until all yearly averages are taken into account as well as seasonally weighted averages.

The commenter also states that in the proposed rule's discussion of meteorological conditions a lower stability level would more likely lead to less dispersion and higher PM–10 values. The commenter believes the lower stability means the PM–10 levels were overestimated and provides information as to the unequal distribution in the surrounding community and who is bearing the brunt of the higher exposures.

Response 21: In our proposed rule we reference the expected PM–10 exceedances from 1990–1992, 1998–2000 and 2002–2004 to show that there has been a significant decline in NAAQS exceedances over the past 17 years, i.e., from 1990 through 2006. There are no data gaps; the 2007 Plan includes data for each year. 2007 Plan at 23–24, Figure 2. EPA believes that a 17 year period is sufficient to establish a trend that accounts for any cyclical changes in PM–10 data. In addition, an evaluation of the seasonal conditions causing PM–10 is provided in the 2003 PM–10 Plan. 2003 PM–10 Plan at ES–4 to ES–10 and Chapter 2.

EPA examined meteorological data, including information about atmospheric stability, wind speeds, precipitation and temperature in order to determine if there were any unusually favorable meteorological conditions that would cause PM–10 exceedances. EPA determined that overall there was no consistent pattern of favorable meteorology. 73 FR 22307, 22312; responses to comments 3 and 6 above.

For the SJVAB area, it has been determined that on an annual average basis, unstable conditions (or low stability) result in dispersion of pollutants and lower PM–10 levels and stable conditions (or high stability) result in a temperature inversion which keeps emissions at the surface and leads to higher PM–10 levels. 2007 Plan at Appendix C. During the attainment period of 2003 through 2006, the SJVAB area experienced somewhat low stability which allowed for dispersion of pollutants and lower PM–10 levels; however, as discussed in response to comment 6 above, based on the analysis of all the meteorological parameters, EPA determined that there was no overall pattern which favored improved PM–10 levels.

It is not completely clear to EPA what point the commenter is trying to make regarding stability. EPA acknowledges, however, that unstable conditions combined with other factors (e.g., emissions) in the SJV area can lead to

[16] Currently there is no FRM or FEM monitoring of PM–10 in the East Kern area. However, there is an Interagency Monitoring of Protected Visual Environments (IMPROVE) monitor located in the Kern River Valley. Pursuant to its commitment, CARB has purchased the new monitor and has secured permission from the Bureau of Land Management to install it next to the existing IMPROVE monitor.

high PM–10 levels on a daily basis, as has been seen with exceedances that occur during high wind events. Such exceedances however have been excluded from regulatory consideration under EPA's Exceptional Events Rule. 73 FR 22307, 22310–22311 and 73 FR 14687.

Comment 22: The SJVAPCD provided comments supporting EPA's proposed actions and also notes a minor typographical error for the proposed transportation conformity budgets found in Table 4 for Merced County for 2005. The SJVAPCD states that the budget should read 39.4 tons per day and not 39.2 tons per day.

Response 22: EPA appreciates the comments and has made the correction in today's final action.

III. Final Actions

For the reasons set forth in the proposed rule and in the responses to comments above, EPA is taking the final actions summarized below:

Having concluded that the State has addressed all the necessary requirements for a revised boundary designation, EPA is approving the State's request under section 107(d)(3)(D) to revise the boundary designation for the SJV PM–10 nonattainment area by splitting the area into two separate serious PM–10 nonattainment areas, the SJVAB PM–10 nonattainment area and the East Kern PM–10 nonattainment area.

Having concluded that the CAA requirements of section 107(d)(3)(E) for redesignations and section 175A for maintenance plans have been met for the SJVAB area, EPA is approving the State's request to redesignate the newly created serious SJVAB nonattainment area to attainment for the PM–10 NAAQS and approving the 2007 maintenance plan for the area.

EPA is also approving the conformity trading mechanism for the SJVAB area and the motor vehicle emissions subarea budgets for the attainment year, 2005, and the maintenance year, 2020, found in Table 3 below. The 2005 attainment year budget replaces the current attainment budgets from the approved 2003 PM–10 Plan. These budgets are approved as of November 12, 2008 pursuant to section 93.118(f)(2)(iii).[17]

TABLE 3—MOTOR VEHICLE EMISSIONS SUBAREA BUDGETS 2007 PLAN *

[Tons per day]

County	2005		2020	
	PM–10	NO_X	PM–10	NO_X
Fresno	13.5	59.2	16.1	23.2
Kern **	12.1	88.3	14.7	39.5
Kings	3.1	16.7	3.6	6.8
Madera	3.6	13.9	4.7	6.5
Merced ***	6.2	39.4	6.4	12.9
San Joaquin	9.1	42.6	10.6	17.0
Stanislaus	5.6	29.7	6.7	10.8
Tulare	7.3	25.1	9.4	10.9
Total	60.5	314.9	72.2	127.6

* The budgets are based on attainment and maintenance of the 24-hour PM–10 NAAQS. The annual standard was revoked on December 18, 2006. See 71 FR 61144.

** MVEBs in Table 3 are only for the SJVAB portion of Kern County.

*** EPA's April 25 and May 23, 2008 proposed rules (73 FR 22307 and 73 FR 30029) incorrectly include 39.2 tons per day for the Merced 2005 NO_X subarea budget. This was a typographical error. The number provided in the State's submittal of the 2007 Plan is 39.4 tons per day, which is reflected in Table 3 above.

EPA is excluding from use in determining that the SJVAB area has attained the PM–10 NAAQS two exceedances that it has concluded were caused by exceptional events on July 4, 2007 and January 4, 2008, and is determining that the SJVAB area continues to attain the PM–10 standard.

Finally, EPA is approving commitments from KCAPCD and CARB to install a FRM or FEM in the newly created East Kern serious PM–10 nonattainment area and to address section 189(d) CAA requirements for the area in a SIP revision in the event the FRM or FEM records a violation of the PM–10 standard.

IV. Statutory and Executive Order Reviews

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 a revised boundary designation, a redesignation to attainment for the SJVAB, a maintenance plan for the SJVAB area, motor vehicle emissions budgets and conformity trading mechanism for the area and commitments for the East Kern area, all of which were either requested or submitted by the State. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule does not impose any additional enforceable duty, 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).

Executive Order 13175 (65 FR 67249, November 9, 2000) requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Seven Indian tribes have

[17] 40 CFR 93.118(f)(2) applies when EPA reviews the adequacy of an implementation plan simultaneously with EPA's approval or disapproval of the implementation plan, as is the case here. Subsection (f)(2)(iii) provides that ''[i]f EPA makes an adequacy finding through a final rulemaking that approves the implementation plan submission, such a finding will become effective upon the publication date of EPA's approval in the **Federal Register**.''

reservations located within the boundaries of the SJVAB. EPA has consulted with representatives of the tribes and will continue to work with the tribes as provided for in Executive Order 13175. Accordingly, EPA has addressed Executive Order 13175 to the extent that it applies to this action. This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves requests or submittals from the State and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency actions by directing agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority and low-income populations. Today's action involves approvals of a revised boundary designation, a redesignation to attainment for the SJVAB area, a maintenance plan for the SJVAB area, motor vehicle emissions budgets and conformity trading mechanism for the area and commitments for the East Kern area. It will not have disproportionately high and adverse effects on any communities in the area, including minority and low-income communities.

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply because it would be inconsistent with applicable law for EPA, when determining the attainment status of an area, to use voluntary consensus standards in place of promulgated air quality standards and monitoring procedures that otherwise satisfy the provisions of the Clean Air. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 12, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2)).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

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

Dated: September 24, 2008.

Wayne Nastri,

Regional Administrator, Region IX.

■ Parts 52 and 81 of Chapter I, Title 40 of the Code of Federal Regulations are 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 F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(356) and (357) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(356) The following plan was submitted on November 16, 2007, by the Governor's Designee.

(i) Incorporation by reference.

(A) San Joaquin Valley Air Pollution Control District.

(*1*) 2007 PM10 Maintenance Plan and Request for Redesignation, adopted by the San Joaquin Valley Air Pollution Control District on September 20, 2007, section 6. Contingency Plan on pages 16 to 17.

(ii) Additional materials.

(A) San Joaquin Valley Air Pollution Control District.

(*1*) 2007 PM10 Maintenance Plan and Request for Redesignation, adopted by the San Joaquin Valley Air Pollution Control District on September 20, 2007, except for Appendices A through F.

(*2*) State of California, Air Resources Board, Staff Report, Analysis of the San Joaquin Valley 2007 PM10 Maintenance Plan, Release Date: October 12, 2007, Appendix B Emission Inventory.

(*3*) Letter dated May 13, 2008, from James N. Goldstene, California Air Resources Board, to Wayne Nastri, EPA, providing revised motor vehicle emission budgets for the 2007 San Joaquin Valley PM10 Maintenance Plan.

(357) The following commitments were submitted on February 29, 2008, by the Governor's Designee:

(i) Incorporation by reference.

(A) Commitments for the installation and operation of a FRM or FEM PM–10 monitor and SIP development and submittal.

(*1*) Resolution No. 2008–001–02, adopted by the Air Pollution Control Board, Kern County Air Pollution Control District on February 27, 2008.

(*2*) Executive Order S–08–004, adopted by the California Air Resources Board on March 3, 2008.

* * * * *

PART 81—[AMENDED]

■ 3. The authority citation for Part 81 continues to read as follows:

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

■ 4. In § 81.305 the ''California—PM–10'' table is amended under Fresno, Kern, Kings, Madera, Merced, San Joaquin, Stanislaus, Tulare Counties by revising the entry for the ''San Joaquin Valley planning area'' to read as follows:

§ 81.305 California.

CALIFORNIA—PM–10

Designated Area	Designation		Classification	
	Date	Type	Date	Type
* * * *	*	*	*	
Fresno, Kern, Kings, Madera, Merced, San Joaquin, Stanislaus, Tulare Counties:				
* * * *	*	*	*	
East Kern; that portion of Kern County which lies between the following two lines (with the exception of that portion in Hydrologic Unit Number 18090205—the Indian Wells Valley): (1) West and north of a line described as follows: Beginning at the southwest corner of section 31, T. 10 N. 16 W. and running east to the northwest boundary of the Rancho La Liebre Land Grant; then running north and east along the northwest boundary of the Rancho La Liebre Land Grant to the point of intersection with the range line common to R. 15 W. and R. 16 W., San Bernardino Base and Meridian; then north along the range line to the northwest corner of section 2, T. 32 S., R. 32 E., Mount Diablo Base and Meridian; then east along the township line common to T. 32 S. and T. 31 S.; then north along the range line common to R. 35 E. and R. 34 E.; then east along the township line common to T. 29 S. and T. 28 S.; then north along the range line common to R. 36 E. and R. 35 E.; then east along the township line common to T. 28 S. and T. 27 S.; then north along the range line common to R. 37 E. and R. 36 E. to the Kern-Tulare County boundary. (2) East and south of a line of a line described as follows: Beginning at the southwest corner of section 31, T. 10 N. 16 W. and running north along the range line common to R. 16 W. and R. 17 W., San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Land Grant to the northwest corner of S. 3, T. 11 N., R. 17 W.; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of S. 34, T. 32 S., R. 30 E., Mount Diablo Base and Meridian; then north to the northwest corner of S. 35, T. 31 S., R. 30 E.; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of S. 18, T. 31 S., R. 31 E.; then east to the southeast corner of S. 13, T. 31 S., R. 31 E.; then north along the range line common to R. 31 E. and R. 32 E., Mount Diablo Base and Meridian, to the northwest corner of S. 6, T. 29 S., R. 32 E.; then east to the southwest corner of S. 31, T. 28 S., R. 32 E.; then north along the range line common to R. 31 E. and R. 32 E. to the northwest corner of S. 6, T. 28 S., R. 32 E., then west to the southeast corner of S. 36, T. 27 S., R. 31 E., then north along the range line common to R. 31 E. and R. 32 E. to the Kern-Tulare County boundary.	11/15/1990	Nonattainment	11/15/1990	Serious.

CALIFORNIA—PM–10—Continued

Designated Area	Designation		Classification	
	Date	Type	Date	Type
San Joaquin Valley Air Basin; Fresno County, Kings County, Madera County, Merced County, San Joaquin County, Stanislaus County, Tulare County, and that portion of Kern County which lies west and north of a line described as follows: Beginning at the Kern-Los Angeles County boundary and running north and east along the northwest boundary of the Rancho La Libre Land Grant to the point of intersection with the range line common to R. 16 W. and R. 17 W., San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Land Grant to the northwest corner of S. 3, T. 11 N., R. 17 W.; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of S. 34, T. 32 S., R. 30 E., Mount Diablo Base and Meridian; then north to the northwest corner of S. 35, T. 31 S., R. 30 E.; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of S. 18, T. 31 S., R. 31 E.; then east to the southeast corner of S. 13, T. 31 S., R. 31 E.; then north along the range line common to R. 31 E. and R. 32 E., Mount Diablo Base and Meridian, to the northwest corner of S. 6, T. 29 S., R. 32 E.; then east to the southwest corner of S. 31, T. 28 S., R. 32 E.; then north along the range line common to R. 31 E. and R. 32 E. to the northwest corner of S. 6, T. 28 S., R. 32 E., then west to the southeast corner of S. 36, T. 27 S., R. 31 E., then north along the range line common to R. 31 E. and R. 32 E. to the Kern-Tulare County boundary.	December 12, 2008.	Attainment.		
*	*	*	*	*	*	*

[FR Doc. E8–26500 Filed 11–10–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0175; FRL–8387–8]

Avermectin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on bean, lima, seed. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on large lima beans. This regulation establishes a maximum permissible level for residues of avermectin in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2010.

DATES: This regulation is effective November 12, 2008. Objections and requests for hearings must be received on or before January 12, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0175. All documents in the docket are listed in the docket index available in *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, 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 also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0175 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 January 12, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0175, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on bean, lima, seed at 0.005 parts per million (ppm). This time-limited tolerance expires and is revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the CFR.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Avermectin on Large Lima Beans and FFDCA Tolerances

The state of California asserts that large lima bean growers have few miticides to work with for controlling spider mites. Confirmed resistance to dicofol has been demonstrated in fields located in Stanislaus County. In 2006, two-spotted spider mite infestations were pervasive on some ranches and some growers experienced 30% crop losses despite use of the available registered alternatives. After having reviewed the submission, EPA determined that emergency conditions exist for this State, and that the criteria for an emergency exemption are met. EPA has authorized under FIFRA section 18 the use of avermectin on large lima beans for control of spider mites in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of avermectin in or on large lima beans. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2010, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on large lima beans after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether avermectin meets FIFRA's registration requirements

for use on large lima beans or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of avermectin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than California to use this pesticide on this crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for avermectin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for combined residues of avermectin B_1 and its delta-8,9-isomer in or on bean, lima, seed at 0.005 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for avermectin used for human risk assessment is discussed in a tolerance document entitled *Avermectin* B_1 *and its delta-8,9-isomer; Pesticide Tolerance* (70 FR 7876, FRL–7695–7, February 16, 2005).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to avermectin, EPA considered exposure under the time-limited tolerance established by this action as well as all existing avermectin tolerances in (40 CFR 180.449). EPA assessed dietary exposures from avermectin in food as follows:

i. *Acute exposure.* In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The following assumptions were made for the acute exposure assessments: A Tier 3, acute probabilistic dietary exposure assessment was conducted for all supported food uses and drinking water. Acute anticipated residues for many foods were derived using market basket survey and new field trial studies. Estimated concentrations of avermectin in drinking water were incorporated directly into the acute assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM/FCID which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. Percent crop treated and anticipated residues refinements were used. A refined chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The assumptions of the assessment were anticipated residue estimates, PCT estimates for most of the commodities, and default DEEM processing factors when necessary. Estimated concentrations of avermectin in drinking water were incorporated directly into the chronic assessment.

iii. *Cancer.* An aggregate exposure assessment for the purpose of assessing cancer risk was not performed because avermectin has been classified as ''not likely to be carcinogenic to humans.''

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food

derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Almonds 21%; avocado 20%; balsam pear 1%; cantaloupe 7%; casabas 1%; chayote fruit 1%; Chinese waxgourd 1%; cotton 3%; cress (garden, upland) 1%; cucumber 1%; grape 6%; hops 82%; honeydew melon 1%; plum 1%; pumpkin 1%; squash 1%; strawberry 44%; walnut 2%; watermelon 7%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which avermectin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for avermectin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of avermectin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*. Tier II screening models PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) were used to determine estimated surface water concentrations of avermectin based on the modeled scenario of one seed treatment to cucumbers followed by 3 aerial applications at a 7–day interval in Florida. This use of avermectin represents the worst case potential contribution of avermectin to drinking water when considering currently registered uses, including this one. The full PRZM/EXAMS distribution was used for the acute dietary assessment, and the one in ten year annual mean concentration of 0.190 ppm was used for chronic dietary estimates. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Avermectin is currently registered for use on the following residential non-dietary sites: Residential lawn application for fire ant control and residential indoor crack and crevice application for cockroaches and ants. These registered residential uses may result in short- to intermediate-term exposures; however, based on current use patterns, long-term exposure (6 or more months of continuous exposure) to avermectin is not expected. Adults may be exposed through handling the pesticide and both adults and children may be exposed through contact with treated areas following application. Accordingly, handler and post-application exposures were assessed for two major categories of residential avermectin use which are considered to represent the reasonable high-end residential exposure potential:

i. Granular baits used to treat lawns, and

ii. Indoor crack and crevice dust products.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found avermectin to share a common mechanism of toxicity with any other substances, and avermectin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that avermectin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor. For avermectin B_1 EPA retained the default 10X factor based on the following combination of factors:

• There is residual uncertainty due to a data gap for a developmental neurotoxicity study (DNT), as well as data gaps for acute and subchronic neurotoxicity studies. These studies are required because avermectin B_1 has been shown to be neurotoxic, with multiple neurotoxic clinical signs (including head and body tremors and limb splay) seen in multiple studies with multiple species.

• For several species, the dose-response curve appears to be steep.

• Severe effects were seen at the LOAELs in several studies (death, neurotoxicity, and developmental toxicity). Although increased susceptibility of the young was observed in several studies, the degree of concern with that susceptibility was judged to be low. Increased susceptibility (qualitative and/or quantitative) was seen in prenatal developmental toxicity studies in CD–1 mice and rabbits following *in utero* exposure to avermectin B_1. There was also an increase in quantitative and qualitative susceptibility in the rat reproductive toxicity study. The concern for susceptibility seen in the developmental study with rabbits and in the reproductive toxicity study in the rat is low because the lowest NOAEL obtained (0.12 mg/kg/day) was used as the basis for the chronic RfD and other non-dietary risk assessment scenarios, which is protective of all of the developmental/offspring effects seen in those studies. Similarly, the concern for susceptibility seen at the LOAEL in the CD–1 mouse developmental toxicity study is low, since the NOAEL in the rat reproductive toxicity study is lower than the dose at which effects were seen in the CD–1 mouse.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to avermectin will occupy 93% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to avermectin from food and water will utilize 20% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of avermectin is not expected.

3. *Short-term and intermediate-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Avermectin is currently registered for uses that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to avermectin.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 3,000 for the U.S. population, and 1,700 for children 1–2 years old. These aggregate MOEs are greater than the Agency's level of concern of 1,000 for aggregate exposure to food, water and residential uses and therefore acceptable.

4. *Aggregate cancer risk for U.S. population*. Avermectin has been classified as ''not likely to be carcinogenic to humans'' and therefore is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to avermectin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX residue limits for residues of avermectin on bean, lima, seed.

VI. Conclusion

Therefore, a time-limited tolerance is established for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on bean, lima, seed at 0.005 ppm. This time-limited tolerance expires and is revoked on December 31, 2010.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under sections 408(e) and 408(l)(6) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal

governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: October 31, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.449 is amended by alphabetically adding a commodity to the table in paragraph (b) to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
bean, lima, seed	0.005	12/31/10
* * * * *		

* * * * *

[FR Doc. E8–26876 Filed 11–12–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0945; FRL–8387–1]

MCPB; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of free and conjugated MCPB and its metabolite MCPA in or on peppermint, tops and spearmint, tops. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 12, 2008. Objections and requests for hearings must be received on or before January 12, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0945. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, 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 also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0945 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 as required by 40 CFR part 178 on or before January 12, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0945, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of October 24, 2007 (72 FR 60369) (FRL–8150–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7257) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.318 be amended by establishing a tolerance for residues of the herbicide MCPB, 4-(2-methyl-4-chlorophenoxy) butyric acid, in or on mint tops (leaves and stems) at 0.25 parts per million (ppm). That notice referenced a summary of the petition prepared by Nufarm, Inc., the registrant, on behalf of IR–4, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the commodity terms and tolerance level. EPA has also revised the tolerance expression to include combined residues of free and conjugated MCPB and its metabolite MCPA. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of free and conjugated MCPB and its metabolite MCPA on peppermint, tops and spearmint, tops at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The currently available toxicological database for MCPB is limited; thus it was supplemented with data on the closely related compound, 4-(chloro-2-methylphenoxy)acetic acid (MCPA). Structurally, MCPB and MCPA differ only in that MCPB contains two additional carbon atoms. In both animal and plant metabolism studies, the data indicate that MCPB is readily converted to MCPA. Therefore, EPA has concluded that the toxicity of these compounds is similar at sub-lethal dose levels.

MCPB has low to moderate acute toxicity via the oral, dermal and inhalation routes of exposure. It is mildly to moderately irritating to the eye but is not a dermal irritant or skin sensitizer. In longer-term studies, nephrotoxicity and hepatotoxicity appear to be the most prevalent hazard concerns for MCPB, based on the effects seen throughout the MCPA database and the limited toxicity data set available for MCPB. Signs of neurotoxicity (decreased arousal, impaired coordination and gait, reduced motor activity and reduced grip strength) were also reported after MCPB or MCPA exposure. Developmental and reproduction toxicity studies conducted with MCPB and/or MCPA did not indicate an enhanced sensitivity or susceptibility of the young, as developmental effects (delayed ossifications and decreased fetal or pup body weight) occurred at the same doses eliciting toxicity in the parental animals (mortality, decreased body weight, body weight gain and food consumption and increased absolute and relative ovary weights). MCPB and MCPA have been classified as ''not likely to be carcinogenic to humans'' based on the absence of increased numbers of tumors in the rat and mouse carcinogenicity studies and no evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by MCPB and MCPA, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, can be found at *http://www.regulations.gov* in the document *4-(4-chloro-2-methylphenoxy)butanoic acid (MCPB); Human-Health Risk Assessment for Proposed Section 3 New Use on Mint*, page 29 in docket ID number EPA–HQ–OPP–2007–0945.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for MCPB used for human risk assessment is shown in the following Table.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MCPB FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children; and females 13–50 years of age)	NOAEL = 200 milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 10x (UF_{DB})	Acute RfD = 0.2 mg/kg/day aPAD = 0.2 mg/kg/day	Acute neurotoxicity (MCPA), rat LOAEL = 400 mg/kg/day based on gait impairment in males
Chronic dietary (All populations)	NOAEL= 4.4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x (UF_{DB})	Chronic RfD = 0.0044 mg/kg/day cPAD = 0.0044 mg/kg/day	Chronic toxicity (MCPA), rat LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Dermal study NOAEL = 25 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	21-Day dermal toxicity (MCPA), rabbit NOAEL = 100 LOAEL = 1,000 mg/kg/day based on kidney toxicity and decreased body weight gain Dermal absorption of MCPB is 4x that of MCPA.
Dermal long-term (> 6 months)	Oral study NOAEL = 4.4 mg/kg/day (dermal absorption rate = 31%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity (MCPA), rat LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL= 5 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity (MCPB), rabbit LOAEL = 20 mg/kg/day based on maternal mortality
Inhalation long-term (> 6 months)	Oralstudy NOAEL = 4.4 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic toxicity (MCPA), rat LOAEL = 17.6 mg/kg/day based on liver and kidney toxicity

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MCPB FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

While the Agency has concluded that MCPB converts to MCPA in the environment, and that MCPA may be present in crops, residues of MCPA resulting from the existing use of MCPB on peas and the new use on mint are expected to be negligible, and significantly below analytical method limits of detection. These residues will not contribute significantly to the aggregate exposure to MCPA from other sources, and, therefore, EPA did not conduct an aggregate assessment combining MCPA exposures from MCPA and MCPB uses. The exposure assessments presented here are for MCPB only. A discussion of aggregate risks associated with MCPA can be found in the MCPA Reregistration Eligibility Decision (RED), available on the Office of Pesticide Programs web site at *http://www.epa.gov/oppsrrd1/REDs/mcpa_red.pdf*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to MCPB, EPA considered exposure under the petitioned-for tolerances as well as the existing MCPB tolerance in 40 CFR 180.318 on peas, the only commodity for which a tolerance currently exists. EPA assessed dietary exposures from MCPB in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that all pea and mint commodities contain tolerance-level residues and that 100 percent of pea and mint commodities are treated with MCPB.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As in the acute exposure assessment, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all pea and mint commodities.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified MCPB as ''not likely to be carcinogenic to humans.'' Therefore, an exposure assessment for evaluating cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for MCPB. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for MCPB in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of MCPB. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of MCPB for acute exposures are estimated to be 54.7 parts per billion (ppb) for surface water and 2.1 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 13.5 ppb for surface water and 2.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 54.7 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

MCPB is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found MCPB to share a common mechanism of toxicity with any other substances, and MCPB does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that MCPB does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for MCPB includes rat and rabbit developmental toxicity studies; for MCPA it includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring to MCPA or MCPB exposure in any of these studies. In the developmental rat studies with MCPB and MCPA, decreased ossification and decreased fetal body weights occurred at the same dose causing maternal effects (decreased body weight gain and food consumption). No toxicity to fetuses occurred in the MCPB and MCPA rabbit developmental studies at doses resulting in maternal toxicity (mortality, decreased body weight and food consumption). In the rat reproduction study for MCPA, the only offspring toxicity was decreased weight gain while nursing, which occurred at the same dose causing maternal toxicity (increased absolute and relative ovary weights).

3. *Conclusion.* EPA has determined that the FQPA safety factor of 10X must be retained as a database uncertainty factor for MCPB acute and chronic risk assessments. This decision is based on the following findings:

i. The toxicity database for MCPB is not complete. Additional data pertaining to MCPB's potential to cause developmental neurotoxicity (DNT) or immunotoxicity are outstanding. EPA's assessment of the uncertainties arising from these data deficiencies follows:

a. *Developmental neurotoxicity:* EPA has required a developmental neurotoxicity study to be submitted because neurotoxicity was found in acute and subchronic neurotoxicity studies with MCPA in rats (decreased arousal, impaired coordination and gait, reduced motor activity, reduced grip strength), and similar signs of neurotoxicity can be expected with MCPB. The neurotoxic effects seen in the acute neurotoxicity studies were the most sensitive acute effect identified and therefore were used in calculating the aRfD for MCPB. Given these findings of neurotoxicity and sensitivity of the neurotoxic effects, EPA has concluded that it lacks reliable data to remove the FQPA 10X safety factor.

b. *Immunotoxicity:* EPA began requiring functional immunotoxicity testing (series 870.7800) of all food and non-food use pesticides on December 26, 2007. Since the requirement went into effect after this tolerance petition was submitted, these studies are not yet available for MCPB. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for MCPB and MCPA regarding potential immunotoxic effects. Evidence of potential immunotoxicity was observed in subchronic 28–day oral toxicity studies in the mouse and dog with MCPA. Involution of the spleen due to lymphocytic depletion was observed in both sexes at the highest dose tested (HDT) and LOAEL of 453.7/223.9 milligrams kilogram day (mg/kg/day) male/female (M/F) in the mouse, and decreased thymus weights were seen in the dog at a dose of 30 mg/kg/day HDT. Lymphoid depletion was observed in the subchronic toxicity study in the dog at a dose of 44 mg/kg/day (HDT) of MCPB. The NOAEL in the mouse and dog for potential immunotoxic effects was 173.4/69.2 mg/kg/day M/F and 20 mg/kg/day, respectively. The NOAEL being used for calculation of the chronic reference dose (cRfD) is 4.4 mg/kg/day. The NOAEL from the mouse study (173.4/69.2 mg/kg/day (M/F)) provides the more appropriate reference for evaluating potential immunotoxic effects in humans. Unlike rodents and humans, dogs are uniquely sensitive to the toxic effects of chlorophenoxy compounds such as MCPB due to their decreased ability to excrete organic acids, and thus the effect levels in the mouse are more relevant to potential immunotoxicity in humans.

After weighing this evidence, EPA retains significant uncertainty regarding potential neurotoxic effects in infants and children but does not have such concerns for immunotoxicity. The immunotoxic effects with most relevance to humans had a NOAEL over 10X greater than the NOAEL used in establishing the cRfD. On the other hand, neurotoxic effects were the most sensitive acute effects seen in the database. Additionally, the DNT study specifically addresses potential risks to developing animals. Given these considerations, EPA has concluded that it lacks reliable data to remove the FQPA children's safety factor.

ii. There is no evidence that MCPB or MCPA results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumption's in the ground and surface water modeling used to assess exposure to MCPB in drinking water, and residential exposures are not expected. These assessments will not underestimate the exposure and risks posed by MCPB.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to MCPB will occupy 5.4% of the aPAD for infants, less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to MCPB from food and water will utilize 22% of the cPAD for infants, less than one year old, the population group receiving the greatest exposure. There are no residential uses for MCPB.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). MCPB is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to MCPB through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). MCPB is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to MCPB through food and

water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. EPA has classified MCPB into the category ''Not Likely to be Carcinogenic to Humans''. MCPB is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to MCPB residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas chromatography/Mass Spectrometry) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for MCPB.

C. Revisions to Petitioned-For Tolerances

IR–4 proposed a tolerance for residues of MCPB *per se* on mint tops (leaves and stems) at 0.25 ppm. EPA has determined that separate tolerances at 0.20 ppm should be established for combined residues of free and conjugated MCPB (4-(4-chloro-2-methylphenoxy)butanoic acid) and MCPA (4-chloro-2-methylphenoxy)acetic acid) on the commodities ''spearmint, tops'' and ''peppermint, tops. The commodity terms were revised to agree with the preferred commodity terms in the Agency's Food and Feed Commodity Vocabulary. EPA determined the appropriate tolerance level for mint tops based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the *Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. Finally, EPA revised the residues of concern to be included in the tolerance expression based on the results of plant metabolism studies.

V. Conclusion

Therefore, tolerances are established for combined residues of free and conjugated MCPB and MCPA in or on peppermint, tops and spearmint, tops at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: October 31, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.318 is amended in paragraph (a) by redesignating the existing text as paragraph (a)(1) and by adding paragraph (a)(2) to read as follows:

180.318 4-(2-Methyl-4-chlorophenoxy) butyric acid; tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for the combined residues, free and conjugated, of the herbicide MCPB, 4-(4-chloro-2-methylphenoxy)butanoic acid, and its metabolite MCPA, (4-chloro-2-methylphenoxy)acetic acid, in or on the following food commodities:

Commodity	Parts per million
Peppermint, tops	0.20
Spearmint, tops	0.20

* * * * *

[FR Doc. E8–26875 Filed 11–10–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 571 and 585

[Docket No. NHTSA–08–0168]

RIN 2127–AK02

Federal Motor Vehicle Safety Standards; Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: NHTSA is amending Federal Motor Vehicle Safety Standard (FMVSS) No. 208, ''Occupant crash protection,'' to update many of the child restraint systems (CRSs) listed in Appendix A of the standard. The CRSs in Appendix A are used by NHTSA to test advanced air bag suppression or low risk deployment systems, to ensure that the air bag systems pose no reasonable safety risk to infants and small children in the real world. The amendments replace the CRSs listed in Appendix A with CRSs that are more available and more representative of the CRS fleet currently on the market.

DATES: If you wish to petition for reconsideration of this rule, your petition must be received by December 29, 2008.

Effective date: The date on which this final rule amends the CFR is January 12, 2009.

This final rule adopts a one-year phase-in of the requirement to test with the child restraints in the revised Appendix A. Under the phase-in, 50 percent of vehicles manufactured on or after September 1, 2009 must be certified as meeting FMVSS No. 208 when tested with the CRSs on the revised Appendix A, and all vehicles manufactured on or after September 1, 2010 must be so certified.

ADDRESSES: If you wish to petition for reconsideration of this rule, you should refer in your petition to the docket number of this document and submit your petition to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., West Building, Washington, DC 20590.

The petition will be placed in the docket. Anyone is able to search the electronic form of all documents received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

FOR FURTHER INFORMATION CONTACT: Carla Cuentas, Office of Crashworthiness Standards, Light Duty Vehicle Division (telephone 202–366–4583, fax 202–493–2739). For legal issues, contact Deirdre Fujita, Office of Chief Counsel (telephone 202–366–2992, fax 202–366–3820). You may send mail to these officials at the National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Washington, DC 20590.

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This final rule amends FMVSS No. 208 to update the child restraint systems (CRSs) listed in Appendix A of the standard. The notice of proposed rulemaking (NPRM) preceding this final rule was published on September 25, 2007 (72 FR 54402; Docket 2007–28710).

I. Background

FMVSS No. 208 (49 CFR 571.208) requires passenger cars and trucks, buses, and multipurpose passenger vehicles with a gross vehicle weight rating (GVWR) of 3,856 kilograms (kg) (8,500 pounds (lb)) or less and an unloaded vehicle weight of 2,495 kg (5,500 lb) or less to be equipped with seat belts and frontal air bags for the protection of vehicle occupants in crashes. While air bags have been very effective in protecting people in moderate and high speed frontal crashes, there have been instances in which they have caused serious or fatal injuries to occupants who were very close to the air bag when it deployed. On May 12, 2000, NHTSA published a final rule to require that air bags be designed to create less risk of serious air bag-induced injuries and provide improved frontal crash protection for all occupants, by means that include advanced air bag technology (''Advanced Air Bag Rule,'' 65 FR 30680, Docket No. NHTSA 00–7013). Under the Advanced Air Bag Rule, to minimize the risk to infants and small children from deploying air bags, manufacturers may suppress an air bag in the presence of a CRS or provide a low risk deployment (LRD) system.[1]

[1] The LRD option involves deployment of the air bag in the presence of a Child Restraint Air Bag Interaction (CRABI) test dummy, representing a 12-month-old child, in a rear-facing child restraint.

To minimize the risk to children, manufacturers relying on an air bag suppression or LRD system must ensure that the vehicle complies with the suppression or LRD requirements when tested with the CRSs specified in Appendix A of the standard. As part of ensuring the robustness of automatic air bag suppression and LRD systems, NHTSA made sure that the appendix contained CRSs that represented a large portion of the CRS market and CRSs with unique size and weight characteristics. NHTSA also planned regular updates to Appendix A.

On November 19, 2003, in response to petitions for reconsideration of the May 2000 Advanced Air Bag Rule, the agency published a final rule that revised Appendix A by adding two CRSs that were equipped with components that attach to a vehicle's LATCH [2] system (68 FR 65179, Docket No. NHTSA 03–16476). The appendix has not been updated since then.

CRSs in Appendix A

Appendix A is made up of four (4) subparts, subparts A through D. There are one (1) car bed, seven (7) rear-facing child restraint systems, nine (9) forward-facing toddler and forward-facing convertible CRSs and four (4) forward-facing toddler/belt positioning booster systems currently listed and deemed ''effective'' (i.e., may be used in compliance testing) in Appendix A.

- Subpart A lists a car bed that can be used by the agency to test the suppression system of a vehicle that is manufactured on or after the effective date specified in Appendix A and that has been certified as being in compliance with 49 CFR 571.208, S19.
- Subpart B lists rear-facing CRSs that can be used by the agency to test the suppression system or the LRD capabilities of a vehicle that is manufactured on or after the effective date and prior to the termination date specified in the appendix and that has been certified as being in compliance with 49 CFR 571.208, S19.
- Subpart C lists forward-facing toddler and forward-facing convertible [3] CRSs that can be used by the agency to test the suppression system or the LRD capabilities of a vehicle that is manufactured on or after the effective date and prior to the termination date specified in the appendix and that has been certified as being in compliance with 49 CFR 571.208, S19 or S21.
- Subpart D lists forward-facing toddler/belt positioning booster systems and belt positioning booster systems that can be used by the agency to test the suppression system capabilities of a vehicle that is manufactured on or after the effective date and prior to the termination date specified in the appendix and that has been certified as being in compliance with 49 CFR 571.208, S21 or S23.

II. Factors for Decision-Making

a. Guiding Factors

The November 2003 FMVSS No. 208 final rule discussed factors that the agency considers in deciding whether Appendix A should be updated (68 FR at 65188). NHTSA reviews the appendix to: Maintain a spectrum of CRSs that is representative of the CRS population in production, ensure that only relatively current restraints will be used for compliance testing, determine the availability of the CRSs and determine any change in design, other than those that are purely cosmetic. (If a change to a CRS were clearly cosmetic, such as color scheme or upholstery, the list would not be modified.) [4] In considering whether a particular restraint should be in Appendix A, the agency considers whether the restraint—

—Has mass and dimensions *representative* of many restraints on the market,
—Has mass and dimensions representing *outliers,* and
—Has been a *high sales volum*e model.

In developing the 2007 NPRM, NHTSA evaluated data, discussed below, and systematically evaluated the CRSs in Appendix A. We assessed child restraint system dimensions, weight (mass) and sales volumes (based on confidential manufacturers' data) to identify which CRSs have dimensions that were representative of the average restraint in today's market, and which were possible outliers, with dimensions, weight [5] and/or footprints [6] markedly outside of those of the ''average'' CRS. In addition, the agency identified which CRSs had high production totals and, therefore, likely to have the greatest market share (highest sales volume).

b. Child Restraint Data

The data used for the NPRM were obtained from CRS manufacturers and NHTSA's Ease-of-Use (EOU) consumer information program. The agency's EOU program started in 2002 in response to the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, which directed NHTSA to issue a notice to establish a child restraint safety rating consumer information program to provide practicable, readily understandable, and timely information to consumers for use in making informed decisions in the purchase of child restraints. The EOU program provides information about child restraints with features that are easier for consumers to use and install correctly. The EOU program seeks to evaluate all CRSs available for sale at retail outlets.

The 2006 EOU program assessed 99 different CRSs (including carryover seats from the previous year that were not changed), selected from 14 different manufacturers (Docket No. NHTSA–2006–25344). In addition to those 99 CRSs, data for the CRSs currently listed in Appendix A were also collected during the 2006 EOU program. These EOU data were used to determine whether any changes to the appendix were warranted.

c. Additional Considerations

The agency believes that Appendix A should include CRSs with a gamut of features that would robustly assess advanced air bag technologies. Automatic air bag suppression systems suppress the air bag when a small child or a child in a CRS is placed on the seat, and enable the air bag's deployment when most adults occupy the seat. With

[2] ''LATCH'' stands for ''Lower Anchors and Tethers for Children,'' a term that was developed by child restraint manufacturers and retailers to refer to the standardized child restraint anchorage system that vehicle manufacturers must install pursuant to FMVSS No. 225, Child Restraint Anchorage Systems (49 CFR § 571.225). The LATCH system is comprised of two lower anchorages and one tether anchorage. Each lower anchorage is a rigid round rod or bar onto which the connector of a CRS can be attached. FMVSS No. 225 does not permit vehicle manufacturers to install LATCH systems in front designated seating positions unless the vehicle has an air bag on-off switch meeting the requirements of S4.5.4 of FMVSS No. 208. Since September 1, 2002, CRSs have been required by FMVSS No. 213, *Child Restraint Systems* (49 CFR § 571.213), to have permanently attached components that enable the CRS to connect to a LATCH system on a vehicle.

[3] A convertible CRS is one that converts from a rear-facing seat to a forward-facing seat. A combination CRS is one that converts from a forward-facing seat to a booster seat or a CRS that is a convertible that can also be used as a booster.

[4] We also stated in the rule that, in considering whether to amend the appendix, we assess whether a variety of restraint manufacturers are represented in the appendix, and whether a combination of restraints are in the appendix. *Id.* These considerations bear on our assessment of the degree to which the CRSs in the appendix are representative of child restraints in the real world and assess the robustness of advanced air bag systems.

[5] Since the CRSs are used to test air bag suppression systems, it was important to identify which CRSs were the lightest and heaviest, and those that are representative of the average restraint in today's market in terms of weight.

[6] Some air bag suppression systems may have trouble sensing a CRS if the footprint is shaped in a way that loads the air bag suppression system sensors or load cells differently than the CRSs for which the suppression system was designed to recognize.

respect to CRSs in Appendix A, LRD systems deploy the air bag in the presence of a CRABI dummy in a rear-facing CRS. The design and calibration of the advanced air bag system used must perform satisfactorily with a wide range of CRSs that could be installed in the vehicle. With that in mind, the NPRM considered the following factors in choosing CRSs for inclusion in Appendix A.

First, with LRD systems for infants already being used in some vehicles, the agency sought to include rear-facing child restraints of varying seat back heights. On the one hand, rear-facing CRSs with relatively low seat back heights could in some circumstances present a more challenging test of an LRD system, especially one consisting of an air bag mounted on the top of the instrument panel, since the back of the CRS presents less of a reaction surface (resistance). With a low back, the air bag could fully pressurize and interact in a fully energized state with the child's head as the bag comes over the top of the CRS seat back. However, recent agency testing indicates that CRSs with high backs provide significant performance challenges to infant LRD systems. Therefore, we sought to include in Appendix A rear-facing and convertible CRSs with seat back heights that range from 12.75 to 27 in [7] [8] to diversify the spectrum of seat back heights.

Second, features such as handles and sunshields of a rear-facing CRS may complicate and challenge the sensing operation of certain advanced air bag systems relying on future technologies such as vision-based advanced air bag systems. To ensure that advanced air bags perform well with all types of rear-facing CRSs, the agency purposefully includes in Appendix A rear-facing CRSs that have handles and sunshields. NHTSA compliance test procedures specify adjustments of the handles and sunshields to the positions specified in the standard to ensure the robustness of the advanced air bag system.

Third, since CRSs have been required to have LATCH components since September 1, 2002, the agency has decided to replace many of the older non-LATCH CRSs in Appendix A with new equivalent LATCH-equipped CRSs from the same manufacturer.[9] On the other hand, when the LATCH requirement became effective in 2002 for child restraints, CRS manufacturers did not significantly change CRS structures or designs. Accordingly, we expect that suppression and LRD systems will react to LATCH and non-LATCH CRSs similarly. In addition, very few vehicles will have lower anchors in the front outboard passenger seat.

III. Proposed Changes

After considering the factors for decision-making discussed in the previous section of this preamble, NHTSA proposed to delete certain CRSs from Appendix A and to add others.[10] The agency noted that some CRSs undergo annual cosmetic changes that result in different model numbers for the new version, and that some of the model numbers of the CRSs in the NPRM could thus be different in the final rule to reflect the latest model number. The agency docketed a document entitled, ''Technical Assessment of Child Restraint Systems for FMVSS No. 208, Occupant Crash Protection, Appendix A,'' that includes dimensional information, pictures, and statistical data on the current CRSs in the appendix and the CRSs proposed for inclusion in the appendix (Docket No. 2007–28710–0002) (hereinafter referred to as the 2007 Technical Assessment).

The agency proposed to delete six (6) existing CRSs and to add five (5) new CRSs (see Table 1 below, which reproduces Table 1 of the NPRM). The reasons for each proposed deletion or addition were discussed in detail in the NPRM and readers may refer to the NPRM for that information (72 FR at 54405–54407). Our proposed deletions were based generally on CRSs that did not offer any unique characteristics, those that were produced in the smallest quantities, or those that have not been in production for some time. If we proposed eliminating a CRS that offered a unique characteristic, we proposed to replace it with a similar CRS. Our proposed additions also sought to include more LATCH-equipped CRSs in the appendix.

In addition, comments were requested on cosmetic replacements of other CRSs in Appendix A (see Table 2 below, which reproduces Table 2 of the NPRM). The reasons for the updates were discussed in detail in the NPRM (72 FR at 54407–54408). These changes primarily would update the older CRSs in the appendix with newer model CRSs that have the same main physical features as the older restraints. To obtain information on whether CRSs in Appendix A could be replaced by newer, more available models with the same relevant physical features as the Appendix A child restraints, we contacted each manufacturer of the listed CRS and asked which of their more recently-produced CRSs could be considered an equivalent replacement for the Appendix A CRS. With one exception related to the Cosco Dream Ride car bed, manufacturers were able to suggest a possible replacement.[11] We decided that the CRSs in the Appendix that have been out of production the longest (i.e., the hardest CRSs to acquire for testing purposes) should be replaced with newer-model CRSs.

TABLE 1—SUMMARY OF PROPOSED DELETIONS AND ADDITIONS TO APPENDIX A

Name	Type	Appendix subpart
Deletions		
Britax Handle With Care #191	Rear-Facing	B.
Century Assura #4553	Rear-Facing	B.
Century Encore #4612	Convertible	C.
Cosco Olympian #02803	Convertible	C.

[7] The upper end of the spectrum (27 in) represents convertible CRSs, which have higher seat back heights than rear-facing-only CRSs.

[8] The height measurement used for the rear-facing CRSs is the height with their base.

[9] The newly added car bed is the only CRS replacement that came from a different manufacturer.

[10] We noted in the November 2003 FMVSS No. 208 final rule that our periodic review of the child restraints in the appendix may cause the number of CRSs contained therein to change slightly as we identify different trends in the use of CRSs from prior periods. We said then that the number of CRSs should not vary by more than 10–20 percent absent any dramatic changes in the design of restraints.

[11] Subpart A of the appendix lists the Cosco Dream Ride car bed which is no longer being manufactured for retail sale. Cosco was unable to suggest a replacement for this CRS because the manufacturer no longer sells car beds to the general public (the CRS is manufactured and sold mainly for special needs accounts). After consulting with the major CRS manufacturers, we only found one car bed that is being manufactured, the Angel Guard Angel Ride. We proposed the Angel Guard Angel Ride as our replacement choice because the CRS is available to the general public.

TABLE 1—SUMMARY OF PROPOSED DELETIONS AND ADDITIONS TO APPENDIX A—Continued

Name	Type	Appendix subpart
Safety 1st Comfort Ride #22–400	Convertible	C.
Britax Expressway ISOFIX	Forward-Facing	C.
Additions		
Graco Snugride	Rear-Facing	B.
Peg Perego Viaggio #IMCC00US	Rear-Facing	B.
Cosco Summit DX #22–260	Forward-Facing	C.
Evenflo Generations #352	Convertible	C.
Graco Safeseat (Step 2)	Combination	C.

TABLE 2—CRSS THAT COULD BE REPLACED WITH SIMILAR, MORE RECENTLY PRODUCED RESTRAINTS, AND WHAT THOSE REPLACEMENTS SHOULD BE

Appendix A subpart	CRS in Appendix A	Type of CRS	Replacement
A	Cosco Dream Ride	Car bed	Angel Guard Angel Ride #AA2403FOF.
B	Cosco Arriva 02–727	Rear-facing	Cosco Arriva #22–013.
C	Britax Roundabout	Convertible	Britax Roundabout #E9L02.
C	Century Encore [12]	Convertible	Graco ComfortSport.
C	Evenflo Horizon V	Convertible	Evenflo Tribute 5 Deluxe #379.
D	Century Next Step	Combination	Graco Cherished Cargo.
D	Cosco High Back Booster	Booster	Cosco Hi Back Booster #22–209.

IV. Comments and Agency Responses on CRSs in Appendix A

The agency received comments on the proposal from the Alliance of Automobile Manufacturers (Alliance),[13] Porsche Cars North America, Inc. (Porsche), TRW Automotive (TRW), Ferrari, General Motors (GM), the Automotive Occupant Restraints Council (AORC), and from community interest groups Safe Ride News and Traffic Safety Projects. Commenters overwhelmingly supported the deletions identified in Table 1 and Table 2 and generally supported the proposed additions identified in the tables, with many suggesting further amendments to Appendix A. Several commenters raised concerns about the effective date. For example, the Alliance stated that it believes that as many as possible of the unavailable CRSs in Appendix A should be replaced with respect to new vehicle models, but manufacturers should be allowed to continue to certify previously certified models using the existing version of the appendix for at least three years.[14] In contrast, Safe Ride News expressed concern that the proposed lead time ''could stretch out the wait before these new CRSs are introduced for testing to Model Year 2010 or later.'' Some commenters asked for clarification of testing issues, and there were a number of ideas suggested for improving the ease and timeliness of future amendments to Appendix A and for selecting the CRSs that should be included in the appendix. These and other issues are addressed in this and the following sections.

Accompanying this final rule is an updated Technical Assessment of Child Restraint Systems that we have placed in the docket for this final rule (''2008 Technical Assessment''). The assessment contains dimensional information and pictures of the CRSs adopted into Appendix A by this final rule, and statistical data of past EOU data.

To improve the clarity of the appendix, we have reformatted the tables of Appendix A and have set forth an Appendix A–1 which incorporates the revisions adopted by this final rule.

a. Deletions

All commenters supported the proposed deletion of the six CRSs from Appendix A (described in Table 1, above). No commenter opposed the deletions. Several commenters suggested that we refresh all the CRSs in the appendix.

Agency Response: We are adopting the proposed deletions for the reasons discussed in the NPRM. Regarding the Britax Expressway ISOFIX, this CRS is removed from Appendix A effective on the date of publication of this final rule.

Deleting and replacing all the CRSs in the appendix is outside the scope of the present rulemaking. However, we concur with the view that circumstances may warrant updating more than 10 to 20 percent of the number of CRSs in the appendix. The allocation of agency

[12] We later realized that reference to the Encore was in error.

[13] The Alliance is made up of BMW group, Chrysler LLC, Ford Motor Company, General Motors, Mazda, Mitsubishi Motors, Porsche, Toyota, and Volkswagen.

[14] In a petition for rulemaking dated April 27, 2007, the Alliance requested NHTSA to amend FMVSS No. 208 to allow manufacturers the option of certifying vehicles to any edition of Appendix A for five model years after the edition first becomes effective. (In its comment to the September 25, 2007 NPRM, the Alliance reduced the suggested 5-year compliance period to 3 years for this effort to revise Appendix A, recognizing that the appendix has not been amended in several years.)

The petition also requested that the agency commit to amending the appendix every three years and revise the view the agency announced in the past that the appendix should be amended annually. The Alliance believes that annual revisions are not needed to protect children because experience has shown that, despite the fact that the appendix has not been amended since 2003, there is no known incident in which a child in a CRS in the front seat of a vehicle equipped with advanced air bags received a serious injury due to the deployment of an air bag. In addition, the Alliance believed that annual updates to the appendix is inconsistent with the realities of the automobile industry, because retesting and recertifying existing vehicle models every year as new CRSs are added to the appendix would, as the petitioner stated, ''create a tremendous burden on manufacturers which * * * [in light of the absence of known injuries to a child caused by an advanced air bag system] would yield little or no safety benefits.'' The petitioner stated that it recognized that ''in the event of some unanticipated safety need, such as the introduction of an entirely new style of CRS that captures a significant portion of the market, the agency could revise the appendix—subject to notice and lead time constraints—without waiting for three years from the prior update.'' The agency is responding to issues raised in the petition both in this final rule, and in a separate rulemaking action.

resources have hampered our periodic updates of the appendix, so it could be prudent for a rulemaking, such as today's final rule, to affect more than 10 to 20 percent of the CRSs in the appendix.

b. Additions (Identified in Table 1)

With the exception of the Peg Perego Viaggio #IMCC00US, the five child restraints that we proposed to add to Appendix A were supported by commenters. Accordingly, with the exception of the Peg Perego Viaggio #IMCC00US, we are adopting the CRSs for the reasons provided in the NPRM. However, several commenters had questions about some of the restraints and requested clarification of the proposal.

1. Proposed Inclusion of Graco Snugride to Subpart B

GM and the Alliance stated that the NPRM did not provide a model number in Table 1 or in the proposed regulatory text, while the preamble and 2007 Technical Assessment denoted model #8643. TRW noted that it observed that myriad variants of the Snugride exist which appear to have essentially similar construction to the #8643 model and which would likely perform identically in suppression or LRD tests.

Agency Response: Our intent was not to provide a model number for this CRS in the regulatory text. The NPRM mistakenly included the model number for the Graco Snugride in the preamble and the 2007 Technical Assessment.

Due to the dynamic nature of the CRS industry, when selecting new CRSs for the appendix, the agency sought to provide, to the extent possible, generic model numbers. The agency's intention was to make it easier for vehicle manufacturers to find the newly added CRSs by providing model numbers that do not specify patterns for soft goods, type of padding, etc., i.e., for items that would not affect the performance of the advanced air bag system. For some CRSs, such as for Evenflo child restraints, this meant requiring simply a number prefix,[15] or just a name, such as for Graco child restraints, but some CRSs required complete model numbers, such as the child restraints produced by Cosco. Thus, for the Graco Snugride no model number was needed.

2. Proposed Inclusion of Peg Perego Primo Viaggio #IMCC00US to Subpart B

Ferrari stated that the model number proposed for this CRS was out of production and recommended the addition of the new model number IMUN00US. TRW stated that the rubber inserts in the belt slots of the Primo Viaggio have a tendency to grab the seat belt webbing, making it difficult to achieve the maximum 134 N belt tension called for in FMVSS No. 208.

Agency Response: We agree to include model IMUN00US instead of IMCC00US. Market data indicate that the model IMCC00US was discontinued in August 2007 and replaced with the new model name and number Peg Perego Primo Viaggio SIP IMUN00US. The changes made for the new version of the Primo Viaggio SIP are a new handlebar shape and more ear/head padding.

NHTSA installed the Peg Perego Primo Viaggio in seventeen (17) model year (MY) 2008 vehicles and found that while the rubber inserts do make it more difficult to achieve the desired belt tension, the desired belt tension is attainable. We note that, to achieve the specified load, the CRS base was pre-loaded prior to installing the CRS onto the base. Since the IMUN00US is similar structurally to the IMCC00US and the specified FMVSS No. 208 belt tension is achievable using the IMUN00US, we are adding the Peg Perego Primo Viaggio SIP IMUN00US to Appendix A. Photographs of the two CRSs can be found in the 2008 Technical Assessment.

3. Proposed Inclusion of the Evenflo Generations #352 to Subpart C

The NPRM characterized the Evenflo Generations as a convertible CRS.

GM and the Alliance stated that this CRS was not on the manufacturer's website. Ferrari and TRW pointed out that this CRS should be classified as a combination CRS. Ferrari stated that it supports the addition of the Evenflo Generations only if it will be exempted from testing in a rearward facing configuration. TRW stated that there were similar models to the CRS, such as the Generations 3521804.

Agency Response: We are adding the CRS to Appendix A, but we agree with Ferrari and TRW that this CRS was categorized incorrectly in the NPRM as a convertible CRS. This CRS is a forward-facing-only combination CRS. Accordingly, it is listed under the booster car seat section of the manufacturer's Web site.

As explained earlier in this preamble, for purposes of Appendix A, Evenflo child restraints can be identified by a generic model number consisting of a number prefix. The #352 model number provided in the NPRM was merely a prefix of the intended model number. To avoid confusion, we have revised the model number to indicate that the actual model number is several digits long and that the 352 was simply a prefix. The similar model observed by TRW beginning with the 352 prefix is thus an acceptable model.

With regard to combination CRSs, Appendix A categories were developed prior to the development of combination CRSs. Therefore, there is not a subpart of the appendix specific to these restraints. These seats can perform as a forward-facing harness restraint as well as a booster seat using a vehicle's seat belt, so they can technically accommodate a one-year-old, three-year-old, and six-year-old dummy. When considering which subpart of the appendix to categorize these seats, we noted that the FMVSS No. 208 advanced air bag system requirements do not require combination CRSs in Subpart C to be tested with the six-year-old dummy. (*See* FMVSS No. 208, S23.) Therefore, to ensure adequate testing of all the modes a combination CRS can be used for, we are listing the Evenflo Generations 352xxxx in both Subparts C and D of Appendix A.

The agency is responding to Ferrari's comment that the CRS should only be used in rearward facing configurations in the section of this preamble entitled, ''Testing Issues.''

4. Proposed Inclusion of Cosco Summit Deluxe #22–260 to Subpart C

GM stated that it could not find a CRS with the precise name and model number provided in the NPRM and suggested the Summit Deluxe High Back Booster Car Seat model 22565 or the Summit High Back Booster Car Seat model 22260, noting that both have very similar appearance and look like the CRS in the photograph in the 2007 Technical Assessment. The Alliance also pointed out that it could not identify any Cosco CRS with the precise name and model number identified in the NPRM. Ferrari supported the addition of the Summit Deluxe ''only if it will be exempted from testing in rearward facing configurations.''

Agency Response: The agency concurs with the GM comment and is adopting the Cosco Summit Deluxe High Back Booster model 22–262 into Subparts C and D of the appendix. A picture and measurements of the CRS can be found in the 2008 Technical Assessment. The agency is responding to Ferrari's comment that the CRS should only be used in rearward facing configurations in the section of this preamble entitled, ''Testing Issues.''

[15] In the appendix, the additional numbers following the prefix are indicated by ''X''s.

5. Proposed Inclusion of the Graco SafeSeat (Step 2) #8B02 to Subpart C

The Alliance stated that this CRS was on the manufacturer's Web site but that the Alliance was advised by Graco that the company has stopped manufacturing a model with the number or will do so in the very near future. The Alliance stated that NHTSA should substitute the new model name/number that Graco will use for this CRS. TRW stated that Model #8B02 was not found at any of six local large retailers, while a very similar model 8B05 was found at a local retailer and an online source was located for this model.

Agency Response: As discussed earlier, we mistakenly included the model number in the preamble. A model number is not needed. A Graco representative (*see* agency ex parte memorandum in the docket for this final rule) confirmed that Graco model numbers identify only cosmetic features and that identifying the shell does not necessitate identifying a model number. Therefore, the Alliance's concerns about that particular model being discontinued or TRW's concern about not finding that particular model at large retail stores is not a problem. (In addition, this CRS was incorrectly categorized as a combination CRS in Table 1 of the NPRM. As stated in the preamble of that document, the child restraint is a forward-facing only CRS.) However, we are adding the word ''Toddler'' to the name because Graco's Web site and the EOU Web site both list this CRS as the Graco Toddler SafeSeat. Thus, this final rule adopts the Graco Toddler SafeSeat Step 2.

c. Updating Other CRSs in Appendix A (Identified in Table 2)

Commenters generally supported the seven changes identified in Table 2 of the NPRM preamble (the same Table 2 above of today's document).

1. Angel Guard Angel Ride #AA2403FOF (Subpart A)

No commenter objected to including this CRS, but TRW stated that it was unable to find a retail source for this CRS. TRW also expressed concern about the size of this CRS because, the commenter believed, vehicles may not have enough seat belt webbing to reach around it with the vehicle seat fully forward. TRW recommended specifying in FMVSS No. 208 that when the vehicle seat belt lacks the length to reach around a CRS, the vehicle seat is moved to the ''first position rearward of full forward where the seat belt will go around the CRS.''

Agency Response: The agency is replacing the Cosco Dream Ride with the Angel Guard Angel Ride AA2403FOF, a car bed with a 3-point harness, for the reasons provided in the NPRM. The CRS can be ordered directly through Angel Guard and through other sources listed on the manufacturer's Web site (*http://www.angel-guard.com*). The agency is responding to TRW's concern about vehicles' having sufficient belt length to encircle the restraint in the section of this preamble entitled, ''Testing Issues.''

2. Cosco Arriva #22–013 (Subpart B)

In their comments, GM and the Alliance stated that they could not find this CRS on the manufacturer's Web site. TRW also could not find any sources for this CRS and was informed that it is being phased out. Furthermore, TRW requested clarification on whether the Arriva 02–727 should be tested with its base.

Agency Response: We are adopting the Cosco Arriva #22–013PAW, a rear-facing CRS with a 5-point harness, to replace its older counterpart as proposed. The Cosco Arriva #22–013PAW is mainly distributed to hospitals, health departments, and child safety businesses or organizations and is not sold at retailers (these CRSs are called ''institutional CRSs''). However, this CRS is easily available to the public as it can be ordered through Cosco or its distributor, National Safety Resources.[16] We will test the CRS with the base 22–999WHO.

3. Britax Roundabout #E9L02 (Subpart C)

The only comment received on this CRS was from TRW, which supported the change. TRW stated that this CRS was found at large retailers.

Agency Response: We are making the proposed change. However, we will refer to the new restraint as the Britax Roundabout E9L02xx; the last two digits of the model number are not needed because they indicate a specific fabric design. The Britax Roundabout E9L02xx is a convertible CRS with a 5-point harness.

4. Graco ComfortSport (Subpart C)

The NPRM requested comments on replacing the Century Encore with the Graco ComfortSport. However, the reference to the Century Encore was a mistake; that CRS was proposed to be deleted from Appendix A.

GM and the Alliance realized the mistake, stating that the Graco ComfortSport is actually a replacement for the Century STE 1000, not the Century Encore. In addition, the Alliance asked for the identification of a model number for the Graco ComfortSport. TRW stated that it was advised that the model number provided in the 2007 Technical Assessment was recalled and that a new version was becoming available. TRW noted that it purchased a ComfortSport 8C00 for evaluation, because it was advised that all ComfortSports have the same shell.

Agency Response: Commenters are correct that we meant the Graco ComfortSport to replace the Century STE 1000. (The Century STE 1000 and the Century Encore have essentially the same shell, thus the ComfortSport could have replaced either of these CRSs.) No commenter opposed the addition of the Graco ComfortSport, a convertible CRS with a 5-point harness. We are thus adopting the proposed change.

As discussed earlier, a model number is not necessary to adequately identify this Graco CRS. However, we note that several ComfortSport models produced between January 2, 2007 and August 31, 2007 were recalled due to possible misrouting of the LATCH belt during assembly. Graco has assured us that new versions are available and that the model numbers of the new versions end in the number two (2). However, there is still no need to specify a model number for this CRS in Appendix A as no substantive changes were made to the CRS that will affect the performance of a suppression or LRD system.

5. Evenflo Tribute V Deluxe #379 (Subpart C)

The NPRM requested comments on replacing the Evenflo Horizon V with the Evenflo Tribute V Deluxe 379. The only comment on this proposed change was from TRW, which stated that it could not find the Evenflo Tribute V Deluxe with the model number provided in the NPRM.

Agency Response: As explained above, the ''379'' is just a prefix that precedes four other digits of the 7-digit model number. We are clarifying the regulatory text to make this clear. Further, we are removing the ''Deluxe'' specification because it only designates the fabric used and the addition of a cup holder, which are features that will not likely affect the performance of a suppression or LRD system. Accordingly, this final rule replaces the Evenflo Horizon V with the Evenflo Tribute V 379xxxx, a convertible CRS with a 5-point harness.

[16] A representative of the manufacturer verified that they are contemplating phasing out this CRS; however, they said that they would continue producing it as long as there was a demand for it (see agency ex parte memorandum in the docket for this final rule).

6. Graco Cherished Cargo (Subpart D)

GM and the Alliance stated that they could not find the Cherished Cargo on the manufacturer's Web site, although several models that share the name Cargo do appear. TRW claimed that Graco advised them that this CRS was discontinued, but that all Cargo models such as the Platinum, Ultra, etc., use the same shell and are very similar. TRW recommended we avoid the Cherished Cargo and choose a different, more readily available model of the Cargo series, such as the Platinum Cargo.

Agency Response: For the reasons of availability raised by the commenters, we are replacing the Century Next Step with the Graco Platinum Cargo, a forward-facing-only combination CRS with a 5-point harness. It will be listed in both Subparts C and D of the appendix. Graco has informed NHTSA that the Cherished Cargo was not discontinued, but that retailers no longer want to carry this CRS in stock (see agency ex parte memorandum in the docket for this final rule). Graco also confirmed that the Platinum Cargo has the same shell as the Cherished Cargo and it is more readily available. As shown in photographs of the Platinum Cargo and the Cherished Cargo, the CRSs are interchangeable (see the 2008 Technical Assessment).

7. Cosco High Back Booster #22–209 (Subpart D)

The NPRM requested comments on replacing the Cosco High Back Booster with the Cosco High Back Booster 22–209. TRW commented that it could not find this seat at any of the six large retailers it searched. They found similar models such as the 22–206 at two of the six retailers.

Agency Response: We are adopting the Cosco High Back Booster 22–209, a forward-facing only combination CRS with a 5-point harness into Subparts C and D of the appendix. As of July 28, 2008, the manufacturer's Web site has a list of retailers for this CRS on its Web site.

V. Compliance Date

Consistent with statements NHTSA made in the November 19, 2003 FMVSS No. 208 final rule regarding lead time (68 FR at 65188), the agency proposed that the compliance date for the proposed changes to Appendix A be the next model year introduced one year after publication of a final rule modifying Appendix A. The agency believed that the lead time would be sufficiently long to provide vehicle manufacturers time to procure the needed child restraints, test vehicles, and certify the air bag systems to FMVSS No. 208, while ensuring the satisfactory performance of vehicles' suppression and LRD systems in an expeditious manner.

This section addresses the following comments relating to the compliance date.

1. The Alliance agreed that the proposed effective date of September 1, 2009 (the beginning of the next model year introduced one year after the anticipated date of publication of the final rule) is reasonable with respect to new vehicle models and to new child protection systems that will be utilized for the first time in MY 2010 (or later) vehicles. However, the commenter stated that requiring vehicle manufacturers to recertify existing vehicles utilizing a different set of CRSs would impose a tremendous burden on those manufacturers. The Alliance urged the agency to provide manufacturers the option of continuing to certify, for at least three years, ''carry-over'' models that were previously certified to the existing version of Appendix A. The commenter stated that, on average, over 75 percent of its members' MY 2010 models will be equipped with ''child protection systems that are identical to those in the equivalent MY 2009 models.'' The commenter stated that in all likelihood these models will be certified using the CRSs on the existing Appendix A, and that requiring them to be certified using the CRSs on the new Appendix would be extremely burdensome, ''even apart from whether the child protection systems in those models would need to be redesigned or recalibrated to assure compliance with the standard.''

Porsche, a member of the Alliance, commented in support of the Alliance's comments, but added that the model lifespan of Porsche vehicles is typically longer than the industry norms, lasting for seven years or more. Thus, Porsche requested that NHTSA allow manufacturers to use the existing version of Appendix A for up to five years following the effective date of the final rule.[17] ''Any shorter time period would likely result in a significant amount of unnecessary testing, especially under circumstances when most or many of the child restraints on the list are being replaced.''

2. GM, an Alliance member, requested that the effective date of the changes in the final rule be no sooner than September 1, 2010. GM submitted confidential information that provided an estimate of ''the amount of work needed to evaluate, potentially modify, and validate'' its carry-over vehicle platforms and believed that the work could not be completed by ''the next model year introduced one year after publication of the final rule.'' GM believed that delaying the effective date until September 1, 2010 would not increase any risks to safety, because it has no indications ''that there are any CRSs in use that do not properly classify'' with their advanced air bag systems.

3. Ferrari addressed the effective date for the Table 2 changes. The commenter stated that there would be an unnecessary burden on the manufacturers if existing vehicles models already certified to comply with the old CRSs in Table 2 have to be certified again for compliance with the new CRSs. Ferrari suggested that NHTSA add a provision to FMVSS No. 208 stating that if a vehicle manufacturer previously certified a vehicle model using an older CRS listed in Table 2 and has so certified prior to the listing of the newer equivalent CRS in Appendix A, then the vehicle manufacturer does not have to retest said vehicle model using the newer CRS. Ferrari believed that ''This approach avoids costly retesting and since the newer CRS is by definition 'equivalent' to the older CRS, there is no negative effect on safety.''

4. In contrast to the above comments, some comments supported the proposed effective date or expressed concern that it was too long. TRW stated that it saw no concerns with the proposed effective date and believed that it provides sufficient time to adopt the requirements of the proposed rule. Safe Ride News believed that the proposed effective date would be ''too long to wait.'' The commenter was concerned that because the appendix has not been updated in years, it is no longer representative of heavier CRSs that have been on the market for several years. Safe Ride News did not consider it an unreasonable request to shorten the lead-time for manufacturers since the new CRSs will not be difficult to acquire.

Agency Response: NHTSA acknowledges that there are competing considerations in updating Appendix A, specifically, the need to have a representative list while maintaining some stability to minimize the certification burden. Having the list reflect real-world use of a variety of child restraints, and ensuring the compatibility of suppression and LRD systems with those restraints, argue for

[17] Porsche noted that its request is similar to the petition for rulemaking from the Alliance requesting NHTSA to provide a five-year period for carry-over models that were certified to the existing version of Appendix A.

expediency. On the other hand, time constraints and costs associated with certification burdens resulting from changes to the appendix dictate that there are limits to how close in time an effective date can be set. Moreover, as part of the exercise of balancing those interests, we also consider the actual effect that the change to Appendix A has on the robustness of the advanced air bag system, i.e., whether the change to the appendix will result in an actual real-world safety improvement.

NHTSA evaluated the 2000–2007 EOU measurement data to determine if there have been significant shifts in the characteristics of CRSs since 2000 and did not observe any indication of definitive shifts in the CRS characteristics pertinent to air bag performance. (See 2008 Technical Assessment.) For the few changes we did observe, the changes do not appear enough to alter an advanced air bag system's performance. NHTSA undertook indicant tests of seventeen (17) MY 2008 vehicles to assist in determining whether the CRSs being added to the appendix would require manufacturers to redesign their advanced air bag systems. (See matrix in the 2008 Technical Assessment.) The tests indicate that the suppression systems will continue to meet FMVSS No. 208 suppression requirements. This finding is consistent with GM's comment that its vehicles continue to classify CRSs correctly when tested with the CRSs newly added to Appendix A.

The agency is currently working on a response to the Alliance's April 2007 petition; therefore, the suggestions of the petitioners that there should be a set lead time period of 3 or 5 years for re-certification of carry-over models will be addressed in a subsequent rulemaking action. However, to address the recertification concerns with respect to this Appendix A update, we have decided that a balancing of the competing interests can be effectively realized by maintaining the compliance date of September 1, 2009 (the beginning of the next model year introduced approximately one year after date of publication of this final rule), while phasing-in the requirement.[18] The effective date and phase-in schedule apply to all vehicles, without differentiation between new and ''carry-over'' models (these are vehicles that were previously certified to the existing Appendix A). Under the phase-in, 50 percent of vehicles manufactured on or after September 1, 2009 must be certified as meeting FMVSS No. 208 when tested with the CRSs on the revised appendix (which we have designated ''Appendix A–1''), and all vehicles manufactured on or after September 1, 2010 must be so certified as meeting FMVSS No. 208 when tested with the Appendix A–1 child restraints. The September 1, 2009 date ensures that suppression and LRD systems will be tested with representative child restraints in an expeditious manner and thus maintains the robustness of the FMVSS No. 208 test and the soundness of the child protection systems, while the phase-in addresses the vehicle manufacturers' certification burdens. Since there are no marked shifts in the dimensional characteristics of CRSs, a phase-in will not have a negative impact on child safety.[19]

The phase-in has a practical effect of permitting 50 percent of carry-over vehicles to continue to certify to the existing appendix for a period, albeit for a shorter period than the Alliance's suggested period of 3 years or Porsche's suggested period of 5 years. (A manufacturer may choose to have new model vehicles or carry-over vehicles of established models, or both, comprise the 50 percent of vehicles that can be phased-in to the requirement to certify to the revised Appendix A.) The ability to carry over a large percentage of its vehicles for a year works to alleviate compliance burdens on manufacturers.

On the other hand, in response to Safe Ride News, we do not agree that the September 1, 2009 date could be moved up. Although the CRSs newly added to Appendix A will be more readily available than the current seats, recertifying to the new appendix will involve more than just procuring the new CRSs. Vehicle manufacturers need time to test and certify their vehicles. Further, as noted above, we have not seen indication of significant shifts in the CRS characteristics pertinent to air bag performance, so there is not a need to expedite the September 1, 2009 date based on potential real-world safety benefits that could be gained.

We are denying Ferrari's suggestion that we specify in FMVSS No. 208 that if a vehicle manufacturer previously certified a vehicle model using an older CRS that was replaced by this final rule by an ''equivalent'' CRS (these CRSs were listed in Table 2 of the NPRM and Table 2 of this preamble), the vehicle manufacturer does not have to retest said vehicle model using the newer CRS. We do not believe that such a provision is necessary or appropriate. NHTSA does not require vehicle manufacturers to undertake any of the testing specified in the FMVSSs; a manufacturer just needs to ensure that its vehicles meet the requirements of the applicable standard when NHTSA tests the manufacturer's vehicles using the procedures specified in the standard. Thus, a manufacturer has the discretion to decide what testing, if any, is needed to certify the vehicle with the updated appendix.

VI. Early Compliance and Picking and Choosing of CRSs

The NPRM proposed to provide manufacturers the option of early compliance with the amended list, i.e., it was proposed that manufacturers may choose to certify their vehicles with the updated Appendix A prior to the effective date of the provision, as long as the manufacturer notifies the agency that it is exercising this option. However, NHTSA proposed that manufacturers choosing the early compliance option would not be permitted to pick and choose among the CRSs that would be newly added by the final rule. Vehicle manufacturers choosing the early compliance option would have to ensure that their vehicles meet the advanced air bag requirements when NHTSA uses all of the newly-added CRSs (along with the CRSs that were not affected by the amendment). NHTSA proposed this limitation to maintain the integrity of the appendix: The child restraints in each appendix are each part of a comprehensive set based on their physical characteristics and as such, should be maintained as a set.

Agency Response: No commenter objected to the proposal, although the Alliance stated that lead time constraints make it very unlikely that any manufacturer will be able to certify its MY 2009 vehicles to the new version, since, the commenter stated, the sales of these vehicles generally commence in the fall of 2008 or earlier. We are ratifying the provisions discussed above without change. Manufacturers may not pick and choose to certify with some CRSs from Appendix A and some from Appendix A–1.

[18] As with all phase-ins, the agency is adopting a reporting and recordkeeping requirement to facilitate the agency's enforcement of the standard. These reporting and recordkeeping requirements will be set forth in 49 CFR Part 585, Subpart D.

[19] We are submitting a request for OMB clearance of the collection of information required under a phase-in (for compliance purposes, manufacturers must keep records of the vehicles certified to the current Appendix A or to the amended Appendix A, and report that information to NHTSA so that the agency knows which CRSs to use to test vehicles to FMVSS No. 208 suppression and LRD requirements). We request comments on the collection of information. See the section of this preamble entitled, ''Regulatory Analyses and Notices.''

VII. Testing Issues

Commenters raised questions relating to how the agency will use the CRSs in Appendix A. These questions are answered below.

a. Positioning of Adjustable Features

TRW recommends that NHTSA specify what position(s) the adjustable features, e.g., adjustable headrests (Evenflo Generations) and positionable ''feet'' (Graco Snugride and Evenflo Discovery Adjust Right), should be in during testing because, the commenter stated, they may affect their installation in a vehicle and/or how the CRS interacts with the vehicle seat, suppression system sensors, or deploying air bags.

Agency Response: We do not agree that minor adjustments need to be specified in the standard. For the FMVSS No. 208 tests conducted with CRSs, the standard's test procedures state that the installer should follow, to the extent possible, the child restraint manufacturer's directions regarding proper installation of the CRS. Those directions generally provide sufficient information to conduct the compliance test. For example, Evenflo's instructions for the Evenflo Generations state that the headrest should be positioned immediately above the harness slots in use. For other adjustments, the standard is silent because the adjustment is irrelevant for the compliance test; it does not matter how the feature is adjusted because the adjustment does not affect the performance results.

For a few adjustments, FMVSS No. 208 specifically overrides the manufacturer's instructions but is clear in its instruction in those instances. For example, the agency's FMVSS No. 208 test procedure (TP 208) does not require that the CRS be at the manufacturer's recommended angle.[20] In its comment on the NPRM, TRW recommended rewording FMVSS No. 208 and TP208 to require that the CRS level indicator, if present, be in the recommended range. We disagree with this suggestion. FMVSS No. 208 does not specifically require that the CRS level indicator be in the recommended range because the use of positioning devices, such as rolled up towels, do not allow repeatable installations.[21]

b. Testing the Car Bed

In its comment on the proposal to adopt the Angel Guard Angel Ride AA2403FOF car bed into Appendix A, TRW was concerned that due to the large size of the car bed, some vehicles may not have enough seat belt length to reach around this CRS with the vehicle seat fully forward. TRW recommended that FMVSS No. 208 state that when the vehicle seat belt length is insufficient to reach around a CRS, the vehicle seat is to be moved to the first position rearward of full forward where the seat belt will go around the CRS.

Agency Response: We agree to add a provision to FMVSS No. 208 to address this concern. However, we note that TRW did not identify whether it was expressing concern about the belt length of a specific vehicle. FMVSS No. 208, S7.1, requires seat belt assemblies to accommodate a 95th percentile adult male with the seat in any position. That standard defines the hip circumference of a 95th percentile adult male as being 47.2 inches (in). The Angel Guard car bed is approximately 53.75 in around its perimeter (based on a width of 21.75 in and two depth measurements of 16 in). While the car bed appears to require 7 in of additional webbing, many vehicle manufacturers provide additional belt length beyond the minimum required by the FMVSS. According to 2007 and 2008 ''Buying a Safer Car'' information,[22] manufacturers that provide longer seat belts typically provide an average of 24.67 in of extra belt length for the right front passenger position. However, for those vehicles that may not have sufficient webbing to reach around the Angel Guard with the seat in the full forward position, we are amending FMVSS No. 208, S20.2.3.2(a), to provide a provision similar to the one in FMVSS No. 208, S20.1.2, which allows the seat to be moved rearward if there is contact by the CRS or test dummy with the instrument panel.

c. Testing Forward-Facing-Only CRSs in Rear-Facing Configurations

Ferrari stated that it supported the addition of forward-facing-only CRSs to subpart C of Appendix A only if the CRSs are excluded from testing in a rear-facing configuration. Ferrari believed that forward-facing-only CRSs should not be used for testing in a rear-facing configuration and that FMVSS No. 208 and subpart C of the appendix should be revised to exclude forward-facing-only CRSs from all types of rear-facing testing. Ferrari also recommended splitting subpart C into two lists, convertibles (C1) and forward-facing-only CRSs (C2), and to revise S20.2.1.1, S20.2.2.1, and S20.4.2 to identify only CRSs from subpart C1.

Agency Response: We partially agree and partially disagree with this comment. In the NPRM we proposed to include the following language, for the *belted* tests under subpart C: ''Any child restraint listed in this subpart that does not have manufacturer instructions for using it in a rear-facing position is excluded from use in testing in a belted rear-facing configuration under S20.2.1.1(a) and S20.4.2.'' This provision already exists in subpart C with regard to S20.2.1.1(a). We proposed expanding the exclusion to S20.4.2 because there are forward-facing-only CRSs in subpart C that cannot be belted in a rear-facing configuration as specified by S20.4.2. Ferrari's comment was supportive of the proposal, and we received no comment in opposition. We are thus adopting the proposed language in the final rule. However, FMVSS No. 208, S20.2.2.1, is an *unbelted* rear-facing configuration test that includes forward-facing-only CRSs as a misuse condition. Since this is an unbelted test, belt routing is not an issue, so forward-facing-only CRSs are not excluded from testing under this rear-facing configuration test. Such an exclusion was not part of the NPRM.

We are not incorporating Ferrari's recommendation to create two sub-categories in Subpart C in this rulemaking, but we will consider it when undertaking future updates of Appendix A.

d. Specifying the Type of Harness Used for Testing

TRW recommends clarifying which type of harness/belt type should be used when testing the CRSs because different types may have been available for the same model number.

Agency Response: We disagree. In the NPRM preamble we specified the

[20] FMVSS No. 208, S20.2.1.5(c) states: ''* * * secure the child restraint by following, to the extent possible, the child restraint manufacturer's directions regarding proper installation of the restraint for the orientation being installed.'' The TP 208–13, Data Sheet 17, Page 111, states: ''Do not use any positioning devices such as towels.'' Therefore, even though the CRS manufacturer's directions specify a recommended angle, achieving it will not be required for compliance tests if the use of positioning devices is necessary.

[21] In the May 12, 2000 Advanced Air Bag Rule, NHTSA acknowledged that some consumers do use rolled up towels or blankets and that manufacturers may need to address this in designing their advanced air bag systems. The agency stated: ''We note that seat-based systems may, however, need to 'read' the presence of a rear-facing infant restraint that has been stabilized with a rolled up towel or blanket in accordance with the restraint manufacturer's instructions. While we will not use such objects in conducting our compliance tests, the presence of a towel or blanket under the most rearward portion of the child restraint is a real world scenario which some seat-based systems may need to accommodate.'' However, for purposes of conducting our compliance tests, as explained above we do not use the towels or blankets.

[22] *http://www.safercar.gov.*

harness type for the CRSs proposed in Table 1 for the reader's convenience. Since the harness type is not an influencing factor in suppression or LRD test results, the harness types specified were just an indication of the type present in the CRSs evaluated, for illustration purposes. The specifications were not intended to be and are not binding as to the specific harness type with which the agency must test. This final rule also specifies in the preamble the harness type for the CRSs newly added to Appendix A for the reader's convenience, and is not meant to require that the CRS with only that type of harness type would be used for compliance testing.

VIII. Suggestions for Future Amendments

Commenters made a number of suggestions for improving the ease and timeliness of future amendments to Appendix A and for selecting the CRSs that should be included in the appendix. The more significant suggestions are addressed below.

a. Publishing a Yearly Bulletin

AORC and TRW suggested the agency should work with CRS manufacturers to publish a ''Bulletin'' annually, which lists suitable equivalent model numbers and/or names to those listed in the appendix.

Agency Response: We do not consider an annual bulletin published by NHTSA necessary or appropriate at this time. For today's final rule we made every effort to ensure that the CRS models we are including in Appendix A will be available, such as by making sure the model numbers we list do not refer to features immaterial to the purposes of the appendix, such as a soft good (i.e., upholstery, fabric) design. This does not preclude industry from working together to identify equivalent CRS models and publishing a yearly bulletin for industry to use.

b. Meaning of ''Available for Purchase''

The Alliance stated that even if the agency adopts the changes to Appendix A proposed in the NPRM,

> it will still be possible that some of the CRSs listed on the revised Appendix A that is ultimately adopted will not be available at the time the final rule is published. The Alliance urges NHTSA to confirm that if that scenario were to occur, it will continue its policy, first articulated in its November 19, 2003 notice, to 'not use the unavailable or altered CRS for compliance testing, and the manufacturers would likewise be relieved of any burden to procure the CRS or use it to test for suppression.' [Footnote omitted.] 68 FR at 65188. Moreover, the Alliance urges the agency to confirm that for a CRS listed on any amended version of Appendix A to be deemed 'available for purchase' (which is the term NHTSA used in the November 2003 notice), it must be available *from its manufacturer* on the date of publication of the final rule promulgating the amendment—as reflected by the manufacturer's Web site or other product information. [Emphasis in text.]

Agency Response: We do not agree that the term ''available for purchase'' means that the child restraint must be available from its manufacturer. The agency considers CRSs to be available for purchase if it can be purchased from any source. Consumers have available to them a multitude of ways of acquiring child restraints in today's marketplace and we believe that the appendix should reflect such real-world acquisition of the restraints, since consumers could reasonably acquire and use the restraint with the advanced air bag system. In addition, after consideration of the statements made in the November 19, 2003 final rule that we would not use a CRS for compliance testing if it were ''unavailable or altered'' on the date of publication of the final rule adopting it into Appendix A, we have concluded that the statement has been overtaken by events in today's context. We cannot imagine a situation where a new CRS that has been added to the appendix will have undergone a significant design change between the time of the proposal and the final rule. CRSs adopted into the appendix are highly unlikely to be unavailable or altered on the date of publication of the final rule adopting them into the appendix since NHTSA works closely with CRS manufacturers to ensure that newly added CRSs are not slated to be unavailable or altered so close in time to the publication of the final rule. Furthermore, if a CRS differs so much on the day of publication of a rule from the CRS that the agency had proposed and intended to adopt, that situation should be addressed in a rulemaking proceeding that would remove the CRS from the appendix or reconsider the merits of its inclusion. For these reasons, we decline to take the narrow view of ''available for purchase'' suggested by the Alliance.

In the NPRM we acknowledged that we were aware that some of the proposed CRSs would likely change model numbers before the publication of this final rule. Therefore, for this final rule, we have verified the model numbers with the CRS manufacturers and the model numbers of some of the CRSs have been updated to reflect the latest information available from the CRS manufacturers.

c. Developing ''Standard'' Models of CRSs

TRW recommended the agency consider working with CRS manufacturers to develop ''standard'' models of each of the CRSs in the appendix. The ''standard'' CRS would be based on a typical model offered for sale by the CRS manufacturer, but would not be subject to change or obsolescence by the manufacturer without notification to the agency and would not be for sale to the public and would be sold only for the purpose of testing and development.

Agency Response: We have considered a similar approach in the past, which we have called the surrogate approach, and have noted some concerns with it. In the November 2003 final rule (68 FR at 65189), we stated that surrogates—

> do not attempt to represent dimensional outliers * * * they cannot ensure the robustness of an automatic suppression system under real world conditions * * * Additionally, without amending FMVSS No. 213 to require restraints to be dimensionally similar to the surrogates, there is no assurance that the surrogates will continue to represent even the average dimensions of restraints on the market.

We continue to have these concerns with surrogates. Also, updating the appendix serves the dual purposes of finding replacement CRSs for those that have become unavailable, and of ensuring that the CRSs listed are representative of those on the market. While developing ''standard'' models would address the availability problems associated with the dynamic nature of the CRS industry, it does not address the identification of new trends or outliers or the representation of average CRSs on the market. Furthermore, such an effort would require a major commitment from the CRS manufacturers and there is no indication that they would be willing or able to pursue such an effort at this time.

d. Define ''Model'' in Child Restraint System Standard

AORC and TRW suggested adopting a formal ''model'' designation system for child restraints in FMVSS No. 213 (49 CFR 571.213) similar to FMVSS No. 209, S4.1(j), to better track any changes to child restraint models that might affect performance in a suppression or LRD test. FMVSS No. 209 requires that each seat belt assembly be permanently and legibly marked or labeled with, among other things, information on the ''model'' of the assembly. FMVSS No. 209 also states that a ''model'' shall consist of a single combination of

webbing having a specific type of fiber weave and construction, and hardware having a specific design, and that webbings of various colors may be included under the same model. The commenters stated that FMVSS No. 213 could be amended to define a ''child restraint model,'' in the following manner: ''A model shall consist of a single combination of shell, base, harness, and vehicle attachment hardware/provisions/routing having a specific design. Webbing and seat upholstery of various colors may be included under the same model.''

Agency Response: The suggestions raised by the commenters will be kept in mind when addressing future Appendix A rulemakings. We note that FMVSS No. 213, S5.5, already requires child restraints to be labeled with the model name or number. Normally, the CRS manufacturers, for their own tracking purposes, indicate with a stamp on the mold or some other type of visual indication when a mold change has been made.

e. Rear-Facing CRSs With High Profiles

Safe Ride News believed that a low seat back height for rear-facing CRSs is an important factor for LRD testing and so, the commenter stated, it is important to include in Appendix A rear-facing CRSs with low profiles. According to the commenter, we should ensure that the appendix include restraints that can be used without a base because restraints with a base tended to have a higher profile.

Agency Response: Seat back height was one of the parameters used by the agency in selecting CRSs for Appendix A. All the rear-facing CRSs in the revised Appendix A come with a base and can be used with or without the base for the purposes of compliance testing. Appendix A has rear-facing and convertible CRSs with seat back heights that range from 12.75 to 27 in.[23] [24] The rear-facing CRSs we are adding to the appendix diversify the spectrum of seat back heights.

We note that contrary to the commenter's belief, agency LRD testing on different car types has indicated that CRSs with high seat back heights can for some designs provide higher injury values than the low profile CRSs. Accordingly, we are keeping CRSs with high seat back heights in our test program.

[23] The upper end of the spectrum (27 in) represents convertible CRSs, which have higher seat back heights than rear-facing-only CRSs.

[24] The height measurement used for the rear-facing CRSs is the height with their base.

IX. Specification of a Manufactured On or After Date for the Newly Added CRSs

In Appendix A–1 we have incorporated the NPRM date, September 25, 2007, as the ''manufactured on or after'' date for the newly added CRSs. This is to distinguish these CRSs from others that may have been manufactured prior to the September date and which may have had slight design differences. (The agency is taking this step only as a precaution; we do not know of any such differences between like-model CRSs manufactured before September 25, 2007 and those studied by the agency and discussed in the NPRM.) The CRSs that are unaffected by this rulemaking are maintaining the December 1, 1999 date.

X. Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This rulemaking document was not reviewed by the Office of Management and Budget under E.O. 12866. It is not considered to be significant under E.O. 12866 or the Department's Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). The costs and benefits of advanced air bags are discussed in the agency's Final Economic Assessment for the May 2000 final rule (Docket 7013). The cost and benefit analysis provided in that document would not be affected by this final rule, since this final rule only adjusts and updates the CRSs used in test procedures of that final rule. The minimal impacts of today's amendment do not warrant preparation of a regulatory evaluation.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* NHTSA has evaluated the effects of this action on small entities. I hereby certify that this final rule will not have a significant impact on a substantial number of small entities. This rule affects motor vehicle manufacturers, multistage manufacturers and alterers, but the entities that qualify as small businesses will not be significantly affected by this rulemaking because they are already required to comply with the advanced air bag requirements. This final rule does not establish new requirements, but instead only adjusts and updates the CRSs used in test procedures of that final rule.

Executive Order 13132

NHTSA has examined today's final rule pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking does not have federalism implications because this final rule does not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Further, no consultation is needed to discuss the preemptive effect of today's rulemaking. NHTSA rules can have preemptive effect in at least two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemptive provision: ''When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.'' 49 U.S.C. 30103(b)(1). It is this statutory command that preempts State law, not today's rulemaking, so consultation would be inappropriate.

Second, in addition to the express preemption noted above, the Supreme Court has also recognized that State requirements imposed on motor vehicle manufacturers, including sanctions imposed by State tort law, can stand as an obstacle to the accomplishment and execution of a NHTSA safety standard. When such a conflict is discerned, the Supremacy Clause of the Constitution makes their State requirements unenforceable. See *Geier* v. *American Honda Motor Co.,* 529 U.S. 861 (2000). NHTSA has not discerned any potential State requirements that might conflict with the final rule, however, in part because such conflicts can arise in varied contexts. We cannot completely rule out the possibility that such a conflict may become apparent in the future through subsequent experience with standard. NHTSA may opine on such conflicts in the future, if warranted.

National Environmental Policy Act

NHTSA has analyzed this final rule for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This final rule contains a collection of information because of the phase-in reporting requirements being established. There is no burden to the general public. We will be submitting a request for OMB clearance for the collection of information required under today's final rule.

These requirements and our estimates of the burden to vehicle manufacturers are as follows:

NHTSA estimates there are 21 manufacturers of passenger cars, multipurpose passenger vehicles, trucks, and buses having a GVWR of 3,856 kg (8,500 lb) or less.

NHTSA estimates that the annual reporting and recordkeeping burden on each manufacturer resulting from the collection of information is one (1) hour.

NHTSA estimates that the annual cost burden on each manufacturer, in U.S. dollars, on each manufacturer will be $35. No additional resources will be expended by vehicle manufacturers to gather annual production information because they already compile this data for their own use.

The purpose of the reporting requirements will be to aid NHTSA in determining whether a manufacturer has complied with the requirements of FMVSS No. 208 during the phase-in of today's requirements.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' There are no voluntary consensus standards that address the CRSs that should be included in Appendix A.

Executive Order 12988

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

Pursuant to this Order, NHTSA notes as follows: The preemptive effect of this final rule is discussed above. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 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 more than $100 million annually (adjusted for inflation with base year of 1995). This final rule will not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually.

Executive Order 13045

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental, health, or safety risk that NHTSA has reason to believe may have a disproportionate effect on children. This rulemaking is not subject to the Executive Order because it is not economically significant as defined in E.O. 12866.

Executive Order 13211

Executive Order 13211 (66 FR 28355, May 18, 2001) applies to any rulemaking that: (1) Is determined to be economically significant as defined under E.O. 12866, and is likely to have a significantly adverse effect on the supply of, distribution of, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This rulemaking is not subject to E.O. 13211.

Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please write to us at the address provided at the beginning of this document.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

List of Subjects

49 CFR Part 571

Imports, Incorporation by reference, Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

49 CFR Part 585

Motor vehicle safety, Reporting and recordkeeping requirements

■ In consideration of the foregoing, NHTSA amends 49 CFR Chapter V as set forth below.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for Part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50.

■ 2. Section 571.208 is amended by adding S14.8, revising S19.2.1, S19.2.2(d), S20.1.1, the introductory text of S20.2.1.1, S20.2.1.6.1(e), S20.2.2.1, S20.2.3.1, S20.2.3.2(a), S20.4.2, S21.2.1, S22.1.1, S22.2.1.4(a), S22.2.1.6.1(f), S23.2.1, and S24.1.1.

■ 3. Section 571.208 is amended by revising Appendix A, by adding Appendix A–1 after Appendix A, and by moving Figures A1 and A2 that are now at the end of Appendix A to follow Appendix A–1.

■ 4. Section 571.208 is amended by revising the headings of Figures A1 and A2 that are now placed after Appendix A–1.

The amended and added text, appendices, and figures read as follows:

§ 571.208 Standard No. 208; Occupant crash protection.

* * * * *

S14.8 *Vehicles manufactured on or after September 1, 2009 and before September 1, 2010.* Vehicles manufactured on or after September 1, 2009 and before September 1, 2010, shall comply with S14.8.1 through S14.8.4. At any time during the production year ending August 31, 2010, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles by make, model and vehicle identification number that have been certified as complying with S19, S21, and S23 (in addition to the other requirements specified in this standard) when using the child restraint systems specified in Appendix A–1 of this standard. The manufacturer's designation of a vehicle as meeting the requirements when using the child restraint systems in Appendix A–1 of this standard is irrevocable.

S14.8.1 Subject to S14.8.2, for vehicles manufactured on or after September 1, 2009, the number of vehicles certified as complying with S19, S21, and S23 when using the child restraint systems specified in Appendix A–1 of this standard shall be not less than 50 percent of:

(a) The manufacturer's average annual production of vehicles subject to S19, S21, and S23 of this standard manufactured on or after September 1, 2006 and before September 1, 2009; or

(b) The manufacturer's production of vehicles subject to S19, S21, and S23 manufactured on or after September 1, 2009 and before September 1, 2010.

S14.8.2 For the purpose of calculating average annual production of vehicles for each manufacturer and the number of vehicles manufactured by each manufacturer under S14.8.1, a vehicle produced by more than one manufacturer shall be attributed to a single manufacturer as provided in S14.8.2(a) through (c), subject to S14.8.3.

(a) A vehicle which is imported shall be attributed to the importer.

(b) A vehicle manufactured in the United States by more than one manufacturer, one of which also markets the vehicle, shall be attributed to the manufacturer which markets the vehicle.

(c) A vehicle produced by more than one manufacturer shall be attributed to any one of the vehicle's manufacturers specified by an express written contract, reported to the National Highway Traffic Safety Administration under 49 CFR part 585, between the manufacturer so specified and the manufacturer to which the vehicle would otherwise be attributed under S14.8.2(a) or (b).

S14.8.3 For the purposes of calculating average annual production of vehicle for each manufacturer and the number of vehicles by each manufacturer under S14.8.1, each vehicle that is excluded from the requirement to test with child restraints listed in Appendix A or A–1 of this standard is not counted.

S14.8.4 Until September 1, 2011, vehicles manufactured by a final-stage manufacturer or alterer could be certified as complying with S19, S21, and S23 when using the child restraint systems specified in Appendix A. Vehicles manufactured on or after September 1, 2011 by these manufacturers must be certified as complying with S19, S21, and S23 when using the child restraint systems specified in Appendix A–1.

* * * * *

S19.2.1 The vehicle shall be equipped with an automatic suppression feature for the passenger air bag which results in deactivation of the air bag during each of the static tests specified in S20.2 (using the 49 CFR Part 572 Subpart R 12-month-old CRABI child dummy in any of the child restraints identified in sections B and C of Appendix A or A–1 of this standard, as appropriate and the 49 CFR Part 572 Subpart K Newborn Infant dummy in any of the car beds identified in section A of Appendix A or A–1, as appropriate), and activation of the air bag system during each of the static tests specified in S20.3 (using the 49 CFR Part 572 Subpart O 5th percentile adult female dummy).

S19.2.2 * * *

(d) Shall be located within the interior of the vehicle and forward of and above the design H-point of both the driver's and the right front passenger's seat in their forwardmost seating positions and shall not be located on or adjacent to a surface that can be used for temporary or permanent storage of objects that could obscure the telltale from either the driver's or right front passenger's view, or located where the telltale would be obscured from the driver's view if a rear-facing child restraint listed in Appendix A or A–1, as appropriate, is installed in the right front passenger's seat.

* * * * *

S20.1.1 Tests specifying the use of a car bed, a rear facing child restraint, or a convertible child restraint may be conducted using any such restraint listed in sections A, B, and C, respectively, of Appendix A or A–1 of this standard, as appropriate. The car bed, rear facing child restraint, or convertible child restraint may be unused or have been previously used only for automatic suppression tests. If it has been used, there shall not be any visible damage prior to the test.

* * * * *

S20.2.1.1 The vehicle shall comply in tests using any child restraint specified in section B and section C of Appendix A or A–1 of this standard, as appropriate, installed in the front outboard passenger vehicle seat in the following orientations:

(a) * * *

(b) * * *

* * * * *

S20.2.1.6.1 * * *

(e) Use the loading device equipped with the loading foot shown in Figure A1 and position it as shown in Figure A2 of Appendix A and Appendix A–1 of this section. The 15±3 degree angle of the loading device illustrated in Figure A2 is determined with an initial preload of 75±25N.

* * * * *

S20.2.2.1 The vehicle shall comply in tests using any child restraint specified in section B and section C of Appendix A or A–1 of this standard, as appropriate.

* * * * *

S20.2.3.1 The vehicle shall comply in tests using any car bed specified in section A of Appendix A or A–1 of this standard, as appropriate.

* * * * *

S20.2.3.2 * * *

(a) Install the car bed following, to the extent possible, the car bed manufacturer's directions regarding proper installation of the car bed. If the seat belt cannot be secured around the car bed, move the seat rearward to the

next detent that allows the belt to be secured around the car bed, or if the seat is a power seat, using only the control that primarily moves the seat fore and aft, move the seat rearward the minimum distance necessary for the seat belt to be secured around the car bed.

* * * * *

S20.4.2 The vehicle shall comply in tests using any child restraint specified in section B and section C of Appendix A or A–1 of this standard, as appropriate.

* * * * *

S21.2.1 The vehicle shall be equipped with an automatic suppression feature for the passenger air bag which results in deactivation of the air bag during each of the static tests specified in S22.2 (using the 49 CFR Part 572 Subpart P 3-year-old child dummy and, as applicable, any child restraint specified in section C and section D of Appendix A or A–1 of this standard, as appropriate), and activation of the air bag system during each of the static tests specified in S22.3 (using the 49 CFR Part 572 Subpart O 5th percentile adult female dummy).

* * * * *

S22.1.1 Tests specifying the use of a forward facing child restraint, including a booster seat where applicable, may be conducted using any such restraint listed in section C and section D of Appendix A or A–1 of this standard, as appropriate. The child restraint may be unused or have been previously used only for automatic suppression tests. If it has been used, there shall not be any visible damage prior to the test. Booster seats are to be used in the manner appropriate for a 3-year-old child of the same height and weight as the 3-year-old child dummy.

* * * * *

S22.2.1.4 * * *

(a) Using the vehicle safety belts as specified in S22.2.1.5 with section C and section D child restraints of Appendix A or A–1, as appropriate, of this section designed to be secured to the vehicle seat even when empty; and

* * * * *

S22.2.1.6.1 * * *

(f) Use the loading device equipped with the loading foot shown in Figure A1 and position it as shown in Figure A2 of Appendix A and Appendix A–1 of this standard. The 15±3 degree angle of the loading device is determined with an initial preload of 75±25 N.

* * * * *

S23.2.1 The vehicle shall be equipped with an automatic suppression feature for the passenger frontal air bag system which results in deactivation of the air bag during each of the static tests specified in S24.2 (using the 49 CFR Part 572 Subpart N 6-year-old child dummy in any of the child restraints specified in section D of Appendix A or A–1 of this standard, as appropriate), and activation of the air bag system during each of the static tests specified in S24.3 (using the 49 CFR Part 572 Subpart O 5th percentile adult female dummy).

* * * * *

S24.1.1 Tests specifying the use of a booster seat may be conducted using any such restraint listed in section D of Appendix A or A–1 of this standard, as appropriate. The booster seat may be unused or have been previously used only for automatic suppression tests. If it has been used, there shall not be any visible damage prior to the test. Booster seats are to be used in the manner appropriate for a 6-year-old child of the same height and weight as the 6-year-old child dummy.

* * * * *

APPENDIX A TO § 571.208—SELECTION OF CHILD RESTRAINT SYSTEMS

This Appendix A applies to vehicles manufactured before September 1, 2009 and to not more than 50 percent of a manufacturer's vehicles manufactured on or after September 1, 2009 and before September 1, 2010, as specified in S14.8 of this standard. This appendix does not apply to vehicles manufactured on or after September 1, 2010.

A. The following car bed, manufactured on or after December 1, 1999, may be used by the National Highway Traffic Safety Administration to test the suppression system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19:

SUBPART A—CAR BED CHILD RESTRAINTS OF APPENDIX A

Cosco Dream Ride 02–719.

B. Any of the following rear-facing child restraint systems specified in the table below, manufactured on or after December 1, 1999, may be used by the National Highway Traffic Safety Administration to test the suppression or low risk deployment (LRD) system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19. When the restraint system comes equipped with a removable base, the test may be run either with the base attached or without the base.

SUBPART B—REAR-FACING CHILD RESTRAINTS OF APPENDIX A

Britax Handle with Care 191.
Century Assura 4553.
Century Smart Fit 4543.
Cosco Arriva 02727.
Evenflo Discovery Adjust Right 212.
Evenflo First Choice 204.
Graco Infant 8457.

C. Any of the following forward-facing child restraint systems, and forward-facing child restraint systems that also convert to rear-facing, manufactured on or after December 1, 1999, may be used by the National Highway Traffic Safety Administration to test the suppression or LRD system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19, or S21. (Note: Any child restraint listed in this subpart that does not have manufacturer instructions for using it in a rear-facing position is excluded from use in testing in a belted rear-facing configuration under S20.2.1.1(a) and S20.4.2):

SUBPART C—FORWARD-FACING AND CONVERTIBLE CHILD RESTRAINTS OF APPENDIX A

Century Encore 4612.
Cosco Olympian 02803.
Britax Roundabout 161.
Century STE 1000 4416.
Cosco Touriva 02519.
Evenflo Horizon V 425.
Evenflo Medallion 254.
Safety 1st Comfort Ride 22–400.

D. Any of the following forward-facing child restraint systems and belt-positioning seats, manufactured on or after December 1, 1999, may be used by the National Highway Traffic Safety Administration as test devices to test the suppression system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S21 or S23:

SUBPART D—FORWARD-FACING CHILD RESTRAINTS AND BELT POSITIONING SEATS OF APPENDIX A

Britax Roadster 9004.
Century Next Step 4920.
Cosco High Back Booster 02–442.
Evenflo Right Fit 245.

APPENDIX A–1 TO § 571.208—SELECTION OF CHILD SYSTEMS RESTRAINT

This Appendix A–1 applies to not less than 50 percent of a manufacturer's vehicles manufactured on or after September 1, 2009 and before September 1, 2010, as specified in S14.8

of this standard. This appendix applies to all vehicles manufactured on or after September 1, 2010.

A. The following car bed, manufactured on or after the date listed, may be used by the National Highway Traffic Safety Administration to test the suppression system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19:

SUBPART A—CAR BED CHILD RESTRAINTS OF APPENDIX A–1

	Manufactured on or after
Angel Guard Angel Ride AA2403FOF	September 25, 2007.

B. Any of the following rear-facing child restraint systems specified in the table below, manufactured on or after the date listed, may be used by the National Highway Traffic Safety Administration to test the suppression or low risk deployment (LRD) system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19. When the restraint system comes equipped with a removable base, the test may be run either with the base attached or without the base.

SUBPART B—REAR-FACING CHILD RESTRAINTS OF APPENDIX A–1

	Manufactured on or after
Century Smart Fit 4543	December 1, 1999.
Cosco Arriva 22–013 PAW and base 22–999 WHO	September 25, 2007.
Evenflo Discovery Adjust Right 212	December 1, 1999.
Graco Infant 8457	December 1, 1999.
Graco Snugride	September 25, 2007.
Peg Perego Primo Viaggio SIP IMUN00US	September 25, 2007.

C. Any of the following forward-facing child restraint systems, and forward-facing child restraint systems that also convert to rear-facing, manufactured on or after the date listed, may be used by the National Highway Traffic Safety Administration to test the suppression or LRD system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S19, or S21. (**Note**: Any child restraint listed in this subpart that does not have manufacturer instructions for using it in a rear-facing position is excluded from use in testing in a belted rear-facing configuration under S20.2.1.1(a) and S20.4.2):

Subpart C—Forward-Facing and Convertible Child Restraints of Appendix A–1

	Manufactured on or after
Britax Roundabout E9L02xx	September 25, 2007.
Graco ComfortSport	September 25, 2007.
Cosco Touriva 02519	December 1, 1999.
Evenflo Tribute V 379xxxx	September 25, 2007.
Evenflo Medallion 254	December 1, 1999.
Cosco Summit Deluxe High Back Booster 22–262	September 25, 2007.
Evenflo Generations 352xxxx	September 25, 2007.
Graco Toddler SafeSeat Step 2	September 25, 2007.
Graco Platinum Cargo	September 25, 2007.
Cosco High Back Booster 22–209	September 25, 2007.

D. Any of the following forward-facing child restraint systems and belt-positioning seats, manufactured on or after the date listed, may be used by the National Highway Traffic Safety Administration as test devices to test the suppression system of a vehicle that has been certified as being in compliance with 49 CFR 571.208 S21 or S23:

Subpart D—Forward-Facing Child Restraints and Belt Positioning Seats of Appendix A–1

	Manufactured on or after
Britax Roadster 9004	December 1, 1999
Graco Platinum Cargo	September 25, 2007
Cosco High Back Booster 22–209	September 25, 2007
Evenflo Right Fit 245	December 1, 1999
Evenflo Generations 352xxxx	September 25, 2007
Cosco Summit Deluxe High Back Booster 22–262	September 25, 2007

Figure A1 to Appendix A and Appendix A-1 of FMVSS No. 208 Regulatory Text: Loading Bar Foot Detail

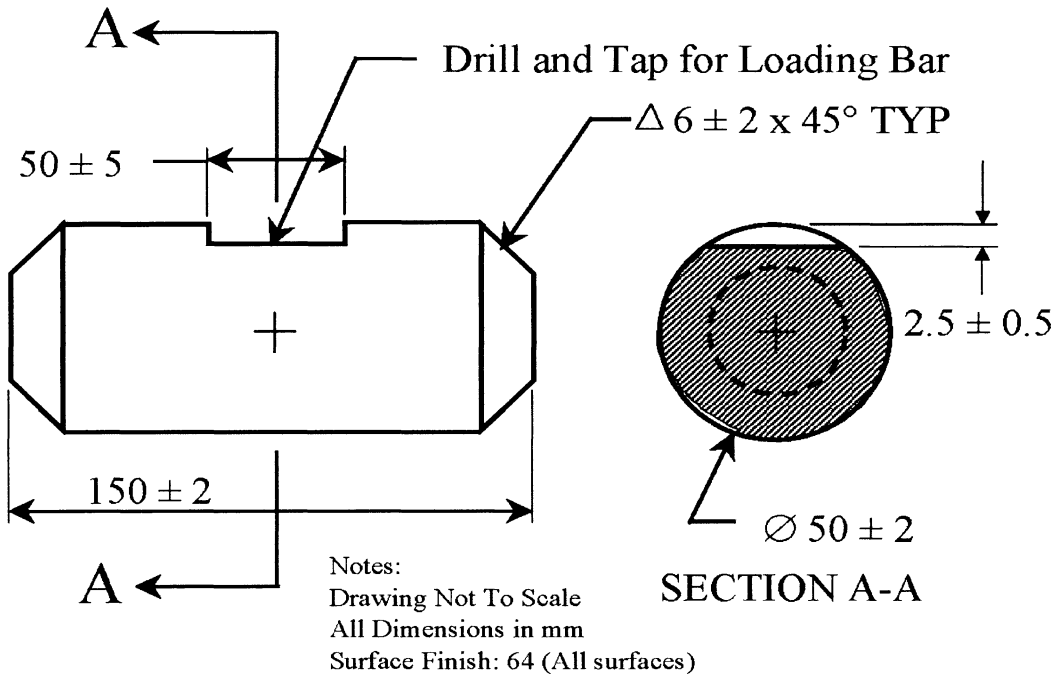
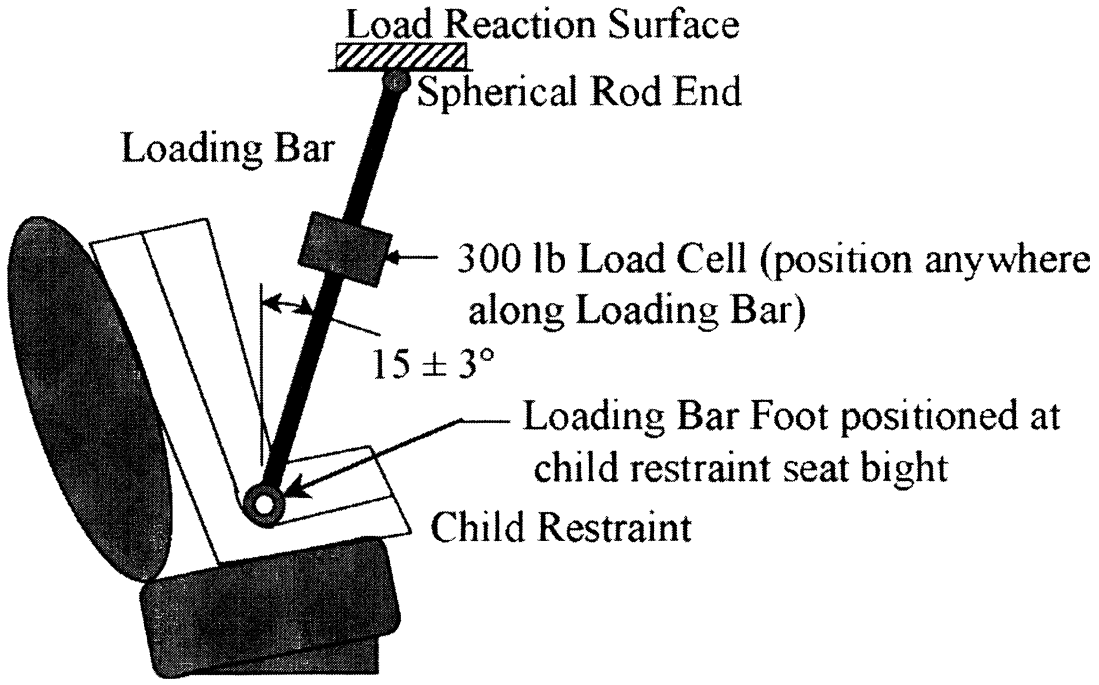


Figure A2 to Appendix A and Appendix A-1 of FMVSS No. 208 Regulatory Text: Loading Bar Installation



■ 3. The authority citation for part 585 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

■ 4. Part 585 is amended by revising Subpart D to read as follows:

PART 585—PHASE-IN REPORTING REQUIREMENTS

* * * * *

Subpart D—Appendix A–1 of FMVSS No. 208 Phase-in Reporting Requirements

585.31 Scope
585.32 Purpose
585.33 Applicability
585.34 Definitions
585.35 Response to inquiries
585.36 Reporting requirements
585.37 Records

* * * * *

§ 585.31 Scope.

This part establishes requirements for manufacturers of passenger cars, and of trucks, buses and multipurpose

passenger vehicles with a gross vehicle weight rating (GVWR) of 3,856 kilograms (kg) (8,500 pounds (lb)) or less, to submit a report, and maintain records related to the report, concerning the number of such vehicles that are certified as complying with S19, S21, and S23 of FMVSS No. 208 (49 CFR 571.208) when using the child restraint systems specified in Appendix A–1 of this standard.

§ 585.32 Purpose.

The purpose of these reporting requirements is to assist the National Highway Traffic Safety Administration in determining whether a manufacturer has complied with the requirements of Standard No. 208 when using the child restraint systems specified in Appendix A–1 of that standard.

§ 585.33 Applicability.

This part applies to manufacturers of passenger cars, and of trucks, buses and multipurpose passenger vehicles with a GVWR of 3,856 kg (8,500 lb) or less.

§ 585.34 Definitions.

(a) All terms defined in 49 U.S.C. 30102 are used in their statutory meaning.

(b) Bus, gross vehicle weight rating or GVWR, multipurpose passenger vehicle, passenger car, and truck are used as defined in § 571.3 of this chapter.

(c) Production year means the 12-month period between September 1 of one year and August 31 of the following year, inclusive.

(d) Limited line manufacturer means a manufacturer that sells three or fewer carlines, as that term is defined in 49 CFR 583.4, in the United States during a production year.

§ 585.35 Response to inquiries.

At any time during the production year ending August 31, 2010, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been certified as complying with the requirements of Standard No. 208 when using the child restraint systems specified in Appendix A–1 of that standard. The manufacturer's designation of a vehicle as a certified vehicle is irrevocable.

§ 585.36 Reporting Requirements.

(a) *Phase-in reporting requirements.* Within 60 days after the end of the production year ending August 31, 2010, each manufacturer shall submit a report to the National Highway Traffic Safety Administration concerning its compliance with requirements of Standard No. 208 when using the child restraint systems specified in Appendix A–1 of that standard for its vehicles produced in that year. Each report shall provide the information specified in paragraph (b) of this section and in section 585.2 of this part.

(b) *Phase-in report content*—

(1) *Basis for phase-in production goals.* Each manufacturer shall provide the number of vehicles manufactured in the current production year, or, at the manufacturer's option, in each of the three previous production years. A new manufacturer that is, for the first time, manufacturing passenger cars, trucks, multipurpose passenger vehicles or buses for sale in the United States must report the number of passenger cars, trucks, multipurpose passenger vehicles or buses manufactured during the current production year.

(2) *Production of complying vehicles.* Each manufacturer shall report on the number of vehicles that meet the requirements of Standard No. 208 when using the child restraint systems specified in Appendix A–1 of that standard.

§ 585.37 Records.

Each manufacturer shall maintain records of the Vehicle Identification Number for each vehicle for which information is reported under § 585.36 until December 31, 2013.

Issued on: October 30, 2008.

David Kelly,

Acting Administrator.

[FR Doc. E8–26812 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1244

[STB Ex Parte No. 385 (Sub-No. 6)]

Waybill Sample

AGENCY: Surface Transportation Board.

ACTION: Final Rule.

SUMMARY: The Board is adopting a final rule to require all carriers that submit carload-waybill-sample information (Waybill Sample) under 49 CFR 1244 to report fuel surcharge revenue in a separate waybill field created by the Board for that purpose, commencing with the Waybill Sample filed for January 2009. The Board will revise the waybill-file-record layout to reflect this change.

DATES: *Effective Dates:* This regulation is effective January 1, 2009. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of January 1, 2009.

FOR FURTHER INFORMATION, CONTACT: Paul Aguiar, (202) 245–0323 or *aguiarp@stb.dot.gov.* [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: A carload waybill is a document describing the characteristics of an individual rail shipment: originating and terminating freight stations, the names of all railroads participating in the movement, the points of all railroad interchanges, the number of cars, the car types, movement weight in hundredweight, the commodity, and the freight revenue. Under 49 CFR Part 1244, a railroad is required to file a Waybill Sample for all line-haul revenue waybills terminating on its lines if, in any of the three preceding years, the railroad terminated 4,500 or more carloads, or it terminated at least 5% of the total revenue carloads that terminate in a particular state.

The Waybill Sample is the Board's primary source of information about freight rail shipments terminated in the United States. Of particular importance, the Board relies on the data in the ''Total Freight LH Revenue'' (also referred to as ''Freight Revenue'') field to compute its ''Revenue Shortfall Allocation Method'' (RSAM) benchmarks. The RSAM benchmarks, which are used in adjudicating certain rate disputes, measure how much a carrier would need to charge its potentially captive traffic in order to obtain adequate revenues overall.

In the last few years, questions have been raised about how railroads reported fuel surcharge revenue in the Waybill Sample. The Board sought to address those questions, and to provide for consistency in the reporting of fuel surcharge revenue in the Waybill Sample, by clarifying that all railroads that are required to submit a Waybill Sample under 49 CFR Part 1244 should report fuel surcharge revenue as part of total freight revenue in the ''Freight Revenue'' field in the waybill-file-record layout. *Waybill Sample,* STB Ex Parte No. 385 (Sub-No. 6) (*Clarification*) (published at 72 FR 72000 on December 19, 2007).

In a request for reconsideration filed on December 31, 2007, the National Industrial Transportation League (NITL) argued that the Board's *Clarification* made it more difficult to identify fuel surcharge revenue in the Waybill Sample and, therefore, did not promote transparency as to the use of fuel surcharges by rail carriers. NITL, with

the support of several other shippers, shipping groups, and other interests, asked the Board to require all carriers that submit a Waybill Sample to report fuel surcharge revenue separately in a Waybill Sample field established for that purpose. No rail carrier objected or even responded to NITL's petition.

In a decision served on June 16, 2008, the Board initiated a rulemaking to require all carriers that submit a Waybill Sample to report fuel surcharge revenue in a separate waybill field created by the Board for that purpose, rather than reporting such revenue within the general freight revenue field, commencing with the Waybill Sample filed for January 2009. The Board reasoned that reporting fuel surcharge revenue in a separate field in the Waybill Sample will increase transparency about the use of fuel surcharges by rail carriers without detracting from the Board's ability to obtain consistent results for the purposes of including such revenue in its RSAM calculations. A notice requesting comments regarding the Board's proposal was published in the **Federal Register** on June 26, 2008 (73 FR 36294). No comments were received.

The Board is adopting the proposed requirement. Statement No. 81–1, Procedure for Sampling Waybill Records by Computer, will be modified to require fuel surcharge revenues to be reported in a new field created for that purpose. The new field (Field 33) will be a 9-byte record. Therefore, the computerized Waybill Sample reported by the railroads will increase from a 228-byte record layout to a 237-byte record layout. To keep reporting consistent within each calendar year, the new field will be required for Waybill Samples commencing with the Waybill Sample filed for January 2009. For consistency and administrative convenience, in addition to reporting in Field 33, carriers are asked to include fuel surcharge revenue as part of total freight revenue in the ''Total Freight LH Revenue'' field (Field 15), as previously directed in *Clarification.*

The Board's decisions in this proceeding are available on the Board's Web site at *www.stb.dot.gov.* Copies of the decisions will also be available for viewing and self-copying in the Board's Public Docket Room, Suite 131, 395 E Street, SW., Washington, DC, or (for a fee) by contacting the Board's Chief Records Officer at (202) 245–0235 or 395 E Street, SW., Washington, DC 20423–0001.

The Director of the Federal Register has approved the Board's request for incorporation by reference of Statement No. 81–1, Procedure for Sampling Waybill Records by Computer (2009 edition). Such approval by the Director requires the insertion of certain language into the regulatory text of the rule as detailed below.

Pursuant to 5 U.S.C. 605(b), the Board certifies that this action will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

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

List of Subjects in 49 CFR Part 1244

Freight, Railroads, Reporting and recordkeeping, Incorporation by reference.

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

Decided: November 3, 2008.

By the Board, Chairman Nottingham, Vice Chairman Mulvey, and Commissioner Buttrey.

Kulunie L. Cannon,

Clearance Clerk.

■ For the reasons set forth in the Supplemental Information above, the Surface Transportation Board amends part 1244 of title 49, chapter X, of the Code of Federal Regulations as follows:

PART 1244—WAYBILL ANALYSIS OF TRANSPORTATION OF PROPERTY—RAILROADS

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

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

■ 2. In § 1244.4, revise paragraph (c) (1) to read as follows:

* * * * *

(c) *The Computerized System.* (1) The tape shall be required to conform to the standards and format specified in Statement No. 81–1, *Procedure for Sampling Waybill Records by Computer* (2009 edition), issued by the Surface Transportation Board. The Director of the Federal Register has approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any editions other than those specified in this section, the STB must publish notice of change in the **Federal Register** and the material must be available to the public. You may obtain or inspect a copy of these standards from the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; from the Surface Transportation Board Web site at *http://www.stb.dot.gov;* or by calling (202) 245–0323. You may also inspect a copy at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

* * * * *

[FR Doc. E8–26570 Filed 11–10–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 222 and 223

[Docket No. 0810061316–81420–02]

RIN 0648–XL11

Sea Turtle Conservation; Shrimp Trawling Requirements

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

ACTION: Temporary rule.

SUMMARY: NMFS issues this temporary rule for a period of 30 days, to allow shrimp fishermen to use limited tow times as an alternative to Turtle Excluder Devices (TEDs) in state waters off of Texas (extending offshore 9 nautical miles from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties; approximately 95° 32' W. long.). The previous 30–day variance of the TED requirements was from October 8 through November 7, 2008. This action is necessary because environmental conditions resulting from Hurricane Ike persist on the fishing grounds, preventing some fishermen from using TEDs effectively.

DATES: Effective from November 8, 2008, through December 7, 2008.

FOR FURTHER INFORMATION CONTACT: Michael Barnette, 727–551–5794.

SUPPLEMENTARY INFORMATION:

Background

All sea turtles that occur in U.S. waters are listed as either endangered or threatened under the Endangered Species Act of 1973 (ESA). The Kemp's ridley (*Lepidochelys kempii*), leatherback (*Dermochelys coriacea*), and hawksbill (*Eretmochelys imbricata*) turtles are listed as endangered. The loggerhead (*Caretta caretta*) and green (*Chelonia mydas*) turtles are listed as threatened, except for breeding populations of green turtles in Florida

and on the Pacific coast of Mexico, which are listed as endangered.

Sea turtles are incidentally taken, and some are killed, as a result of numerous activities, including fishery-related trawling activities in the Gulf of Mexico and along the Atlantic seaboard. Under the ESA and its implementing regulations, the taking of sea turtles is prohibited, with exceptions identified in 50 CFR 223.206(d), or according to the terms and conditions of a biological opinion issued under section 7 of the ESA, or according to an incidental take permit issued under section 10 of the ESA. The incidental taking of turtles during shrimp or summer flounder trawling is exempted from the taking prohibition of section 9 of the ESA if the conservation measures specified in the sea turtle conservation regulations (50 CFR 223) are followed. The regulations require most shrimp trawlers and summer flounder trawlers operating in the southeastern United States (Atlantic area, Gulf area, and summer flounder sea turtle protection area, see 50 CFR 223.206) to have a NMFS-approved TED installed in each net that is rigged for fishing to allow sea turtles to escape. TEDs currently approved by NMFS include single-grid hard TEDs and hooped hard TEDs conforming to a generic description, the flounder TED, and one type of soft TED—the Parker soft TED (see 50 CFR 223.207).

TEDs incorporate an escape opening, usually covered by a webbing flap, which allows sea turtles to escape from trawl nets. To be approved by NMFS, a TED design must be shown to be 97 percent effective in excluding sea turtles during testing based upon specific testing protocols (50 CFR 223.207(e)(1)). Most approved hard TEDs are described in the regulations (50 CFR 223.207(a)) according to generic criteria based upon certain parameters of TED design, configuration, and installation, including height and width dimensions of the TED opening through which the turtles escape.

The regulations governing sea turtle take prohibitions and exemptions provide for the use of limited tow times as an alternative to the use of TEDs for vessels with certain specified characteristics or under certain special circumstances. The provisions of 50 CFR 223.206(d)(3)(ii) specify that the NOAA Assistant Administrator for Fisheries (AA) may authorize compliance with tow time restrictions as an alternative to the TED requirement if the AA determines that the presence of algae, seaweed, debris, or other special environmental conditions in a particular area makes trawling with TED-equipped nets impracticable. The provisions of 50 CFR 223.206(d)(3)(i) specify the maximum tow times that may be used when tow time limits are authorized as an alternative to the use of TEDs. Each tow may be no more than 55 minutes from April 1 through October 31 and no more than 75 minutes from November 1 through March 31, as measured from the time that the trawl doors enter the water until they are removed from the water. These tow time limits are designed to minimize the level of mortality of sea turtles that are captured by trawl nets not equipped with TEDs.

Recent Events

On September 5 and 15, 2008, NMFS received requests from the Louisiana Department of Wildlife and Fisheries (LDWF) and the Mississippi Department of Marine Resources (MDMR), respectively, to allow the use of tow times as an alternative to TEDs in state and Federal waters because of excessive storm-related debris on the fishing grounds as a result of Hurricanes Gustav and Ike. When a TED is clogged with debris, it can no longer catch shrimp effectively nor can it effectively exclude turtles. Phone conversations between NMFS staff, fishermen, and the states' resource agency staffs confirmed there were problems with debris in state and Federal waters off Louisiana (from the Mississippi/Louisiana boundary to the Texas/Louisiana boundary) extending offshore 20 nautical miles, which were likely to affect the effectiveness of TEDs; discussions between NMFS Southeast Region's Protected Resources staff, fishermen, and the states' resource agency staffs, and a survey of Mississippi waters found no significant remaining issues stemming from storm-related debris on the shrimp fishing grounds. Subsequent to these requests, NMFS issued a 30–day exemption to the TED requirements from September 26 through October 26, 2008, for waters off of Louisiana affected by Hurricanes Gustav and Ike (73 FR 57010, October 1, 2008).

On September 29, 2008, the NMFS Southeast Regional Administrator received a request from the Texas Parks and Wildlife Department (TPWD) to allow the use of tow times as an alternative to TEDs in state and federal waters because of excessive storm-related debris on the fishing grounds as a result of Hurricane Ike. Subsequent to this request, NMFS issued a 30–day exemption to the TED requirements from October 8 through November 7, 2008, for waters off of Texas affected by Hurricane Ike (73 FR 60638, October 14, 2008). Specifically, the affected waters encompassed by that exemption extended from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties (approximately 95° 32' W. long.), and offshore 20 nautical miles.

On October 20, 2008, NMFS received a request from the LADWF for an additional 30–day period allowing the use of restricted tow times as an alternative to TEDs in inshore and offshore waters because of excessive storm-related debris that was still present on the fishing grounds as a result of Hurricanes Gustav and Ike. Subsequent to this request, NMFS issued a 30–day exemption to the TED requirements from October 29 through November 28, 2008, for waters off of Louisiana affected by Hurricanes Gustav and Ike (73 FR 65277, November 3, 2008). Specifically, the waters affected extend from the western end of Timbalier Island (approximately 90° 33' W. long.) eastward to the Plaquemines/Jefferson Parish line (approximately 89° 54' W. long.), and offshore 15 nautical miles.

On October 31, 2008, the NMFS Southeast Regional Administrator received a request from the TPWD for an additional 30–day period allowing the use of restricted tow times as an alternative to TEDs in inshore and offshore waters because of excessive storm-related debris that is still present on the fishing grounds as a result of Hurricane Ike. Texas has stated that their marine enforcement agents will enforce the tow time restrictions.

Field investigations and interviews conducted by NMFS Gear Technicians and phone conversations between NMFS Southeast Region's Protected Resources staff, fishermen, and state resource agency staff confirm there are problems with debris in state waters off of Texas. Available information indicates the debris field extends offshore 9 nautical miles from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties; approximately 95° 32' W. long. Investigations conducted by NMFS indicate some shrimp fishermen continue to use TEDs in these areas as the TED is able to exclude debris from the trawl; however, these investigations also indicated there are still significant amounts of large debris that can and does render TEDs ineffective at releasing turtles. These investigations also indicate that most offshore fishermen are using their TEDs due to the fact the debris offshore is of a nature and size that the TEDs can ''shoot'' the debris from the trawl.

Special Environmental Conditions

The AA finds that debris washed into hurricane-affected state waters off of Texas, extending offshore 9 nautical miles from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties (approximately 95° 32' W. long.), has created special environmental conditions that make trawling with TED-equipped nets impracticable. Therefore, the AA issues this notification to authorize the use of restricted tow times as an alternative to the use of TEDs in state waters off of Texas extending offshore 9 nautical miles from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties (approximately 95° 32' W. long.), for a period of 30 days. Tow times must be limited to no more than 75 minutes, as measured from the time that the trawl doors enter the water until they are removed from the water.

Continued Use of TEDs

NMFS encourages shrimp trawlers in the affected areas to continue to use TEDs if possible, even though they are authorized under this action to use restricted tow times.

NMFS' gear experts have provided several general operational recommendations to fishermen to maximize the debris exclusion ability of TEDs that may allow some fishermen to continue using TEDs without resorting to restricted tow times. To exclude debris, NMFS recommends the use of hard TEDs made of either solid rod or of hollow pipe that incorporate a bent angle at the escape opening, in a bottom-opening configuration. In addition, the installation angle of a hard TED in the trawl extension is an important performance element in excluding debris from the trawl. High installation angles can trap debris either on or in front of the bars of the TED; NMFS recommends an installation angle of 45E, relative to the normal horizontal flow of water through the trawl, to optimize the TED's ability to exclude turtles and debris. Furthermore, the use of accelerator funnels, which are allowable modifications to hard TEDs, is not recommended in areas with heavy amounts of debris or vegetation. Lastly, the webbing flap that is usually installed to cover the turtle escape opening may be modified to help exclude debris quickly: the webbing flap can either be cut horizontally to shorten it so that it does not overlap the frame of the TED or be slit in a fore-and-aft direction to facilitate the exclusion of debris. The use of the double cover flap TED will also aid in debris exclusion.

All of these recommendations represent legal configurations of TEDs for shrimpers fishing in the affected areas. This action does not authorize any other departure from the TED requirements, including any illegal modifications to TEDs. In particular, if TEDs are installed in trawl nets, they may not be sewn shut.

Alternative to Required Use of TEDs

The authorization provided by this rule applies to all shrimp trawlers that would otherwise be required to use TEDs in accordance with the requirements of 50 CFR 223.206(d)(2) who are operating in hurricane-affected state waters off Texas, extending offshore 9 nautical miles from the Texas/Louisiana boundary southward to the boundary shared by Matagorda and Brazoria Counties (approximately 95° 32' W. long.), for a period of 30 days. Through this temporary rule, shrimp trawlers may choose either restricted tow times or TEDs to comply with the sea turtle conservation regulations, as prescribed above.

Alternative to Required Use of TEDs; Termination

The AA, at any time, may withdraw or modify this temporary authorization to use tow time restrictions in lieu of TEDs through publication of a notice in the **Federal Register**, if necessary to ensure adequate protection of endangered and threatened sea turtles. Under this procedure, the AA may modify the affected area or impose any necessary additional or more stringent measures, including more restrictive tow times, synchronized tow times, or withdrawal of the authorization if the AA determines that the alternative authorized by this rule is not sufficiently protecting turtles or no longer needed. The AA may also terminate this authorization if information from law enforcement, state authorities, or NMFS indicates compliance cannot be monitored effectively. This authorization will expire automatically on December 7, 2008, unless it is explicitly extended through another notification published in the **Federal Register**.

Classification

This action has been determined to be not significant for purposes of Executive Order 12866.

The AA has determined that this action is necessary to respond to an environmental situation to allow more efficient fishing for shrimp, while providing effective protection for endangered and threatened sea turtles pursuant to the ESA and applicable regulations.

Pursuant to 5 U.S.C. 553(b)(B), the AA finds that there is good cause to waive prior notice and opportunity to comment on this rule. The AA finds that unusually high amounts of debris are creating special environmental conditions that make trawling with TED-equipped nets impracticable. Prior notice and opportunity to comment are impracticable and contrary to the public interest in this instance because providing notice and comment would prevent the agency from providing the affected industry relief from the effects of Hurricane Ike in a timely manner, while continuing to provide effective protection for sea turtles.

Many fishermen may be unable to operate under the special environmental conditions created by Hurricane Ike without an alternative to the use of TEDs. Therefore, The AA finds that there is good cause to waive the 30–day delay in effective date pursuant to 5 U.S.C. 553(d)(3) to provide alternatives to comply with the sea turtle regulations in a timely manner. For the reasons above, the AA finds that this temporary rule should not be subject to a 30–day delay in effective date, pursuant to 5 U.S.C. 553(d)(1).

Since prior notice and an opportunity for public comment are not required to be provided for this action by 5 U.S.C. 553, or by any other law, the analytical requirements of 5 U.S.C. 601 *et seq.* are inapplicable.

Dated: November 6, 2008.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E8–26850 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106673–8011–02]

RIN 0648–XL68

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Processors Using Hook–and–Line Gear in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher processors using hook–and–line gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2008 Pacific cod total allowable catch (TAC) allocated to catcher processors using hook–and–line gear in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 7, 2008, through 2400 hrs, A.l.t., December 31, 2008.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson–Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2008 Pacific cod TAC allocated to catcher processors using hook–and–line gear in the BSAI is 73,844 metric tons (mt) as established by the 2008 and 2009 final harvest specifications for groundfish in the BSAI (73 FR 10160, February 26, 2008). See § 679.20(a)(7)(ii), § 679.20(c)(3)(iii), and § 679.20(c)(5).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that the 2008 Pacific cod directed fishing allowance allocated to catcher processors using hook–and–line gear in the BSAI has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher processors using hook–and–line gear in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by catcher processors using hook–and–line gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 5, 2008.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by section 679.20 and is exempt from review under Executive Order 12866.

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

Dated: November 6, 2008.

Emily H. Menashes

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

[FR Doc. E8–26847 Filed 11–6–08; 4:15 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 73, No. 219
Wednesday, November 12, 2008

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2007–0153]

RIN 0579–AC88

Importation of Eggplant From Israel

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to allow the importation of commercial shipments of fresh eggplant from Israel. As a condition of entry, the eggplant would be grown under a systems approach that would include requirements for pest exclusion at the production site, fruit fly trapping inside and outside the production site, and pest-excluding packinghouse procedures. The eggplant would also be required to be accompanied by a phytosanitary certificate issued by the Israeli national plant protection organization with an additional declaration confirming that the eggplant had been produced in accordance with the proposed requirements. This action would allow for the importation of commercial consignments of fresh eggplant from Israel into the United States while continuing to provide protection against the introduction of quarantine pests.

DATES: We will consider all comments that we receive on or before January 12, 2009.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0153* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2007–0153, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0153.

Reading Room: 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Donna L. West, Senior Import Specialist, Commodity Import Analysis and Operations, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 734–8758.

SUPPLEMENTARY INFORMATION:

Background

The regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–47, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

The Israeli national plant protection organization (NPPO) has requested that the Animal and Plant Health Inspection Service (APHIS) amend the regulations to allow fresh eggplant (*Solanum melongena* L.) to be imported from Israel into the continental United States. As part of our evaluation of Israel's request, we prepared a pest risk assessment (PRA) and a risk management document (RMD). Copies of the PRA and the RMD may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** or viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The PRA, titled ''Evidence-based, Pathway-Initiated Risk Assessment of the Importation of Fresh Eggplant, *Solanum melongena*, from Israel into Continental United States'' (March 26, 2008), evaluates the risks associated with the importation of fresh eggplant into the continental United States (the lower 48 States and Alaska) from Israel.

The PRA and supporting documents identified six pests of quarantine significance present in Israel that could be introduced into the United States through the importation of fresh eggplant. These include the Mediterranean fruit fly (Medfly, *Ceratitis capitata*); *two moths, Helicoverpa armigera and Spodoptera littoralis; a mite, Eutetranychus orientalis; a mealybug, Nipaecoccus viridis; and a thrips, Scirtothrips dorsalis*.

APHIS has determined that measures beyond standard port of arrival inspection are required to mitigate the risks posed by these plant pests. Therefore, we are proposing to allow the importation of fresh eggplant from Israel into the continental United States only if the eggplant is produced under a systems approach. The systems approach would require that the eggplant be grown in approved production sites in pest-exclusionary structures, would require trapping inside and outside the pest-exclusionary structures for Medfly, and would require packinghouse procedures designed to exclude all six quarantine pests. Consignments of eggplant from Israel would also be required to be accompanied by a phytosanitary certificate with an additional declaration stating that the eggplant had been produced in accordance with the proposed requirements. Only commercial consignments of eggplant would be allowed to be imported from Israel.

The mitigation measures in the proposed systems approach are discussed in greater detail below.

Approved Production Sites

The eggplant would have to be grown in pest-exclusionary structures in approved production sites in the Arava Valley of Israel by growers registered with the Israeli NPPO. The Israeli NPPO and APHIS would have to jointly approve of the production sites. The pest-exclusionary structures would have to be equipped with double self-closing doors to prevent inadvertent introduction of pests into the pest-exclusionary structures. In addition, any vents or openings in the pest-exclusionary structures (other than the

double self-closing doors) would have to be covered with screening 1.6 mm or smaller in order to prevent the entry of pests into the pest-exclusionary structure. The 1.6 mm maximum screening size is adequate to exclude all pests of quarantine significance named earlier in this docket except for the thrips species. However, even the thrips species is at least partially discouraged by the physical barrier of the 1.6 mm mesh and the resultant reduced velocity of wind currents upon which they are borne. In addition, because thrips are external feeders, they would most likely be detected during inspection of the pest-exclusionary structures for quarantine pests.

We would require that the pest-exclusionary structures be inspected periodically by the Israeli NPPO or its approved designee to ensure that sanitary procedures are employed to exclude plant pests and diseases and to verify that the screening is intact.

The pest-exclusionary structures would also have to be inspected monthly for the six quarantine pests listed earlier by the Israeli NPPO or its approved designee, beginning 2 months before harvest and continuing for the duration of the harvest. APHIS would have to be granted access in order to monitor or inspect the pest-exclusionary structures during this period as well. If, during these inspections, quarantine pests were found inside the pest-exclusionary structure, the Israeli NPPO would have to immediately prohibit that pest-exclusionary structure from exporting eggplants to the continental United States and notify APHIS of the action. The prohibition would remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated.

Trapping for Medfly

Trapping for Medfly would be required both inside and outside the pest-exclusionary structures. Trapping would have to begin 2 months before harvest and continue for the duration of the harvest.

APHIS-approved traps, with an approved protein bait, would have to be placed inside the pest-exclusionary structures at a density of four traps per hectare, with a minimum of at least two traps per pest-exclusionary structure. The traps would have to be serviced at least once every 7 days. If a single Medfly was found in a trap inside a pest-exclusionary structure, the Israeli NPPO would have to immediately prohibit that pest-exclusionary structure from exporting eggplant to the United States and notify APHIS of the action. The prohibition would remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated. Measures we might use to mitigate the risk include delimiting the source of the infestation, increasing trap density, applying pesticide sprays, or other measures acceptable to APHIS to prevent further occurrences.

In order to reduce the pest pressure of Medfly outside the pest-exclusionary structures, no shade trees would be permitted within 10 meters of the entry door of the pest-exclusionary structures, and no fruit fly host plants would be permitted within 50 meters of the entry door of the pest-exclusionary structures. While trapping is being conducted, no fruit fly host material (such as fruit) would be allowed to be brought into the pest-exclusionary structures or discarded within 50 meters of the entry door of the pest-exclusionary structures. A treatment jointly approved by the Israeli NPPO and APHIS would have to be applied in the areas of the Arava Valley where fruit fly host material occurs in backyards, in order to reduce the Medfly population. This treatment would have to be applied for the duration of the eggplant harvest. Trapping for Medfly would have to be conducted by the Israeli NPPO or its approved designee throughout the year in the agricultural region along the Arava Highway 90 and in the residential area of Paran. These trapping records would have to be kept and made available to APHIS for review upon request.

Packinghouse Procedures

The eggplant would have to be packed within 24 hours of harvest in a pest-exclusionary packinghouse. While packing the eggplant for export to the continental United States, the packinghouse would only be allowed to accept eggplant from approved pest-exclusionary structures. As with the pest-exclusionary structures, no shade trees would be permitted within 10 meters of the entry door of the packinghouse, and no fruit fly host plants would be permitted within 50 meters of the entry door of the packinghouse. The eggplant would have to be safeguarded by a pest-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing. Packinghouse procedures would have to include culling of any visibly damaged, overripe, or infested eggplant.

The eggplant would have to be packed for shipment to the continental United States in either individual insect-proof cartons or boxes labeled with the specific place of origin or non-insect-proof cartons or boxes that are covered by insect-proof mesh or plastic tarpaulins. Covered non-insect-proof cartons or boxes would have to be placed in shipping containers that have identification labels indicating the specific place of origin. Labeling the cartons or boxes and/or containers with the place of origin would facilitate traceback if necessary and help ensure that only shipments from approved pest-exclusionary structures are shipped to the continental United States. These safeguards would have to remain intact until the arrival of the eggplant in the continental United States or the consignment would not be allowed to enter the continental United States. These safeguards would prevent the eggplant from being infested with plant pests during departure from the approved pest-exclusionary structures until its arrival in the continental United States.

Commercial Consignments

Only commercial consignments of eggplant from Israel would be allowed to be imported into the United States. Produce grown commercially is less likely to be infested with plant pests than noncommercial consignments. Noncommercial consignments are more prone to infestations because the commodity is often ripe to overripe, could be of a variety with unknown susceptibility to pests, and is often grown with little or no pest control. Commercial consignments, as defined in § 319.56–2, are consignments that an inspector identifies as having been imported for sale and distribution. Such identification is based on a variety of indicators, including, but not limited to: Quantity of produce, type of packaging, identification of grower or packinghouse on the packaging, and documents consigning the fruits or vegetables to a wholesaler or retailer.

Phytosanitary Certificate

To certify that the eggplant has been produced in accordance with the mitigations described in this document, we would require that each consignment of eggplant be accompanied by a phytosanitary certificate of inspection issued by the Israeli NPPO bearing an additional declaration that reads ''The eggplant in this consignment has been grown in an approved production site and inspected and found free of the pests listed in 7 CFR 319.56–48.'' These proposed provisions governing the importation of eggplant from Israel would be added to the regulations as a new § 319.56–48.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to allow the importation of commercial shipments of fresh eggplant from Israel. As a condition of entry, the eggplant would have to be grown under a systems approach that would include requirements for pest exclusion at the production site, fruit fly trapping inside and outside the production site, and pest-excluding packinghouse procedures. The eggplant would also be required to be accompanied by a phytosanitary certificate issued by the Israeli NPPO with an additional declaration confirming that the eggplant had been produced in accordance with the proposed requirements. This action would allow for the importation of commercial consignments of fresh aeggplant from Israel into the United States while continuing to provide protection against the introduction of quarantine pests.

Eggplant, which is native to India and Pakistan, is a warm-season crop that is sensitive to cool temperatures. World production of eggplant is highly concentrated, with 83 percent of output by the top two producers, China (55 percent) and India (28 percent), and with the United States a distant 20th in production.

According to the 2002 Census of Agriculture, there were 50,000 farms in 47 States that may produce, among other vegetables, some eggplant, but only about 4 percent of the 50,000 farms reported harvesting eggplant. In all, about 7,000 acres are devoted to eggplant production in the United States, with 72 percent of eggplant production taking place in 11 counties in 4 States: California, Florida, Georgia, and New Jersey (table 1). In addition, 63 percent of the number of acres planted in eggplant in the United States are in these four States. Production at a much lower level takes place in other States including Hawaii, Michigan, and New York.

TABLE 1—2006 STATE-LEVEL PRODUCTION OF EGGPLANTS IN THE UNITED STATES

States/counties	Eggplant production (metric tons)	Number of acres planted with eggplants
California (Fresno and Riverside)	17,690.11	1,364.
Florida (Palm Beach, Hillsborough, Dade)	15,875.74	1,174.
Georgia (Colquitt, Echols, Lowndes)	14,870.75	1,100.
New Jersey (Gloucester, Cumberland, Atlantic)	11,748.05	800.
Sum of 4 States	60,184.65 (72% of production)	4,438 (63% of planted area).
United States	83,914.61	7,000.

Source: United States Department of Agriculture (USDA), Economic Research Service (ERS), Vegetables and Melons Situation and Outlook Yearbook, December 2006; U.S. Census of Agriculture, 2002.

Despite a per-capita consumption rate of less than 1 pound, the United States is the leading importer of eggplant in the world, accounting for 20 percent of world eggplant import volume.[1] The next largest eggplant importers are France with 15 percent, Syria with 12 percent, Germany with 11 percent, and Canada with 9 percent of world eggplant import volume. These 5 countries account for 67 percent of world eggplant imports. The remaining 33 percent of world eggplant imports is divided among the rest of the world. Between 2004 and 2006, the United States imported on average $45 million worth of eggplant (table 2).

Most U.S. eggplant imports enter during the cooler months of the year. Florida is the only domestic shipper during the winter.[2]

TABLE 2—U.S. TRADE OF FRESH EGGPLANTS, 2004–2006

	U.S. imports	U.S. exports	Net imports
Value in thousand dollars			
2004	$49,028	$8,148	$40,880
2005	45,981	8,735	37,246
2006	39,986	8,943	31,043
Quantities in metric tons			
2004	49,768.4	9,669.1	40,099.3
2005	54,096.8	9,660.5	44,436.3
2006	49,065.0	9,626.2	39,438.8

Source: U.S. Department of Commerce, Bureau of Census, as reported by Global Trade Information Services. **Note**: Based on the Harmonized Schedules 070930.

[1] Vegetables and Melons Outlook/VGS–318/ December 14, 2006, Economic Research Service, U.S. Department of Agriculture (pages 23–27).

[2] On average, during 2004–06, the winter season (January–March) accounted for 55 percent of U.S. eggplant imports; the spring season (April–June) accounted for 20 percent; the summer season (July–September) accounted for 5 percent; and, the fall season (October–December) accounted for 31 percent.

Impact on Small Entities

U.S. entities that could be affected by the proposed rule are domestic producers of fresh eggplant and wholesalers that import fresh eggplant. Businesses producing fresh eggplant are classified in the North American Industry Classification System (NAICS) within the category of other vegetable (except potato) and melon farming (NAICS 111219). The Small Business Administration's (SBA) small-entity standard for this category is $750,000 or less in annual receipts. While available data do not provide the number of U.S. eggplant-producing entities or information on the size distribution of U.S. eggplant-producing entities, it is reasonable to assume that the majority of the operations are small by SBA standards, based on the fact that the average vegetable farm is small.

Israel is a small exporter of eggplant. For example, in 2006 Israel's exports of commercial shipments of fresh eggplant were valued at only $20,000. This value is only 0.05 percent of the value of U.S. eggplant imports in 2006 (nearly $40 million). In other words, even if all of Israel's 2006 worldwide eggplant exports are diverted entirely to the United States, they would represent a negligible share of total U.S. imports and an even smaller share of the U.S. eggplant supply.

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

Executive Order 12988

This proposed rule would allow eggplant to be imported into the continental United States from Israel. If this proposed rule is adopted, State and local laws and regulations regarding eggplant imported under this rule would be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, *Attention:* Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2007–0153. Please send a copy of your comments to: (1) Docket No. APHIS–2007–0153, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

APHIS is proposing to allow the importation of commercial consignments of fresh eggplant from Israel. As a condition of entry, the eggplant would be grown under a systems approach that would include requirements for pest exclusion at the production site, fruit fly trapping inside and outside the production site, and pest-excluding packinghouse procedures. The eggplant would also be required to be accompanied by a phytosanitary certificate issued by the Israeli national plant protection organization with an additional declaration confirming that the eggplant had been produced in accordance with the proposed requirements. This action would allow for the importation of commercial consignments of fresh eggplant from Israel into the United States while continuing to provide protection against the introduction of quarantine pests.

Implementing this information collection will allow respondents to complete various documents such as trapping records, labeling of boxes, inspection, and phytosanitary certificates.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as 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).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.0047 hours per response.

Respondents: Importers of eggplants, foreign officials (non-government).

Estimated annual number of respondents: 18,005.

Estimated annual number of responses per respondent: 1.0031.

Estimated annual number of responses: 18,061.

Estimated total annual burden on respondents: 85 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS's Information Collection Coordinator, at (301) 851–2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS's Information Collection Coordinator, at (301) 851–2908.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. A new § 319.56–48 is added to read as follows:

§ 319.56–48 Eggplant from Israel.

Eggplant (*Solanum melongena* L.) may be imported into the continental United States from Israel only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: *Ceratitis capitata, Eutetranychus orientalis, Helicoverpa armigera, Nipaecoccus viridis, Scirtothrips dorsalis, and Spodoptera littoralis*.

(a) *Approved pest-exclusionary structures*. The eggplant must be grown in pest-exclusionary structures in approved production sites in the Arava Valley of Israel by growers registered with the Israeli national plant protection organization (NPPO). Initial approval of the production sites must be completed jointly by the Israeli NPPO and APHIS.

(1) The pest-exclusionary structures must be equipped with double self-closing doors.

(2) Any vents or openings in the pest-exclusionary structures (other than the double self-closing doors) must be covered with 1.6 mm or smaller screening in order to prevent the entry of pests into the pest-exclusionary structure.

(3) The pest-exclusionary structures must be inspected periodically by the Israeli NPPO or its approved designee to ensure that sanitary procedures are employed to exclude plant pests and diseases and to verify that the screening is intact.

(4) The pest-exclusionary structures also must be inspected monthly for the quarantine pests listed in the introductory text of this section by the Israeli NPPO or its approved designee, beginning 2 months before harvest and continuing for the duration of the harvest. APHIS must be granted access to inspect or monitor the pest-exclusionary structures during this period as well. If, during these inspections, any quarantine pests listed in the introductory text of this section are found inside a pest-exclusionary structure, the Israeli NPPO will immediately prohibit that pest-exclusionary structure from exporting eggplant to the continental United States and notify APHIS of the action. The prohibition will remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated.

(b) *Trapping for Medfly*. Trapping for Mediterranean fruit fly (Medfly, *Ceratitis capitata*) is required both inside and outside the pest-exclusionary structures. Trapping must begin 2 months before harvest and continue for the duration of the harvest.

(1) *Inside the pest-exclusionary structures*. APHIS-approved fruit fly traps with an approved protein bait must be placed inside the pest-exclusionary structures at a density of four traps per hectare, with a minimum of at least two traps per pest-exclusionary structure. The traps must be serviced at least once every 7 days. If a single Medfly is found in a trap inside a pest-exclusionary structure, the Israeli NPPO will immediately prohibit that pest-exclusionary structure from exporting eggplant to the continental United States and notify APHIS of the action. The prohibition will remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated.

(2) *Outside the pest-exclusionary structures*. (i) No shade trees are permitted within 10 meters of the entry door of the pest-exclusionary structures, and no fruit fly host plants are permitted within 50 meters of the entry door of the pest-exclusionary structures. While trapping is being conducted, no fruit fly host material (such as fruit) may be brought into the pest-exclusionary structures or be discarded within 50 meters of the entry door of the pest-exclusionary structures.

(ii) A treatment jointly approved by the Israeli NPPO and APHIS must be applied for the duration of the eggplant harvest in the areas of the Arava Valley where fruit fly host material occurs in backyards.

(iii) Trapping for Medfly must be conducted by the Israeli NPPO or its approved designee throughout the year in the agricultural region along the Arava Highway 90 and in the residential area of Paran.

(iv) Trapping records must be kept and made available for APHIS review upon request.

(c) *Packinghouse procedures*. The eggplant must be packed within 24 hours of harvest in a pest-exclusionary packinghouse. While packing the eggplant for export to the continental United States, the packinghouse may only accept eggplant from approved pest-exclusionary structures. No shade trees are permitted within 10 meters of the entry door of the packinghouse, and no fruit fly host plants are permitted within 50 meters of the entry door of the packinghouse. The eggplant must be safeguarded by a pest-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing. Packinghouse procedures must include culling of any visibly damaged, overripe, or infested eggplant. The eggplant must be packed in either individual insect-proof cartons or boxes labeled with the specific place of origin or non-insect-proof cartons or boxes that are covered by insect-proof mesh or plastic tarpaulins. Covered non-insect-proof cartons or boxes must be placed in shipping containers that have identification labels indicating the specific place of origin. These safeguards must remain intact until the arrival of the eggplant in the continental United States or the consignment will not be allowed to enter the continental United States.

(d) *Commercial consignments*. Eggplant from Israel may be imported in commercial consignments only.

(e) *Phytosanitary certificate*. Each consignment of eggplant must be accompanied by a phytosanitary certificate of inspection issued by the Israeli NPPO with an additional declaration reading as follows: ''The eggplant in this consignment has been grown in an approved production site and inspected and found free of the pests listed in 7 CFR 319.56*48.''

Done in Washington, DC, this 5th day of November 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–26814 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2008–N–0561]

Maximum Civil Money Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to amend our regulations to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended. The last adjustment was published in the **Federal Register** of July 20, 2004 (69 FR 43299), and the FCPIAA requires Federal agencies to adjust their civil money penalties at least once every 4 years. This proposed rule does not adjust the civil money provisions

enacted by the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on the proposed rule by December 26, 2008. If FDA receives any timely significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice-and-comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0561, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. FDA–2008–N–0561 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In general, the FCPIAA (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as: '' * * * the percentage (if any) for each civil monetary penalty by which—(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law'' (28 U.S.C. 2461 note, section 5(b)).

The FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the first adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as: ''any penalty, fine, or other sanction that—(A)(i) is for a specific monetary amount as provided by Federal law; or (ii) has a maximum amount provided for by Federal law; and (B) is assessed or enforced by an agency pursuant to Federal law; and (C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts'' (28 U.S.C. 2461 note, section 3(2)).

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

In the **Federal Register** of July 20, 2004 (69 FR 43299), we published a final rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The final rule amended our regulations governing civil money penalties hearings found at part 17 (21 CFR part 17) to establish a new § 17.2 entitled ''Maximum penalty amounts'' to show the maximum civil monetary penalty amounts that were adjusted under the FCPIAA. The final rule also revised § 17.1, which lists statutory provisions authorizing civil money penalties governed by the civil money penalty regulations as of August 28, 1995, updating the statutory citations.

II. What Changes Did We Make?

We revised the list of statutory monetary penalties in § 17.1 to include the new penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended by FDAAA in 2007. These new penalties have been added as proposed new paragraphs (c) and (d). The table in § 17.2 has also been amended to include the new penalties, and the adjusted maximum penalty amounts for the pre-FDAAA penalties have been updated to account for the inflation between June 2004 (the year of the last adjustment) and June 2007 as prescribed by FCPIAA. The per violation amount for 21 U.S.C. 333(f)(1)(A), the per violation per person amount for 21 U.S.C. 360pp(b)(1), and the per violation amount for 42 U.S.C. 263b(h)(3) have not been adjusted because the rounding rules of FCPIAA prevent an inflation adjustment in these cases. The new FDAAA penalties have also not been adjusted because Congress only recently passed FDAAA on September 27, 2007. Finally, the ''Description of the Violation'' column in the table in § 17.2 is proposed to be removed, as it is unnecessary for purposes of merely showing the adjustment in penalty amounts.

III. What is Proposed?

In brief, the proposed rule would:

- Revise § 17.1 to update the statutory citations regarding the new civil monetary penalties prescribed by FDAAA, and
- Revise the table in § 17.2 to include the new FDAAA penalties, and adjusts the pre-FDAAA maximum civil penalty amounts for inflation as prescribed by FCPIAA.

IV. Additional Information

This proposed rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a

regulation implementing inflation adjustments for all its civil penalty provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which civil penalties are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. In addition, FDA has made conforming changes to the regulations, which have no substantive effect, to reflect the new penalties prescribed by Congress in FDAAA.

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical in substance. This companion proposed rule will provide the procedural framework to proceed with standard notice-and-comment rulemaking in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule and vice versa.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to the companion proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends. We intend the direct final rule to become effective 30 days after publication of the confirmation document.

If we receive significant adverse comments, we will withdraw the direct final rule. We will proceed to respond to all the comments received regarding the direct final rule, treating those comments as comments to this proposed rule. The agency will address the comments in the subsequent final rule. We will not provide additional opportunity for comment. If we receive a significant adverse comment which applies to part of the rule and that part may be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of significant adverse comment.

For additional background information, see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**.

V. Environmental Impact

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

VI. Paperwork Reduction Act 1995

We conclude that the civil monetary penalties adjustments in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule simply proposes to adjust the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

2. Section 17.1 is amended by redesignating paragraphs (c) through (g) as paragraphs (e) through (i) and by adding new paragraphs (c) and (d) to read as follows:

§ 17.1 Scope.

* * * * *

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

* * * * *

3. Section 17.2 is revised to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period	2008	1,200,000
333(b)(3)	110,000	Per violation	2008	120,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000
333(f)(2)(A)	55,000	Per individual	2008	60,000
333(f)(2)(A)	275,000	Per "any other person"	2008	300,000
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted)
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected	2007	10,000 (not adjusted)
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted)
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2007	250,000 (not adjusted)
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted)

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for ''any other person''	2008	1,200,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26864 Filed 11–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–222P]

RIN 1117–AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing that chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, be automatically exempt from regulatory controls under the Controlled Substances Act (CSA). DEA is seeking through this rulemaking to exempt only those chemical mixtures that do not represent a significant risk of diversion. If finalized as proposed, this regulation would result in GBL chemical mixtures, in concentrations greater than 70 percent, becoming subject to List I chemical regulatory requirements of the CSA, except if exempted through an existing categorical exemption. DEA is taking this action because there is a serious threat to the public safety associated with the ease by which GBL is chemically converted to the schedule I controlled substance gamma-hydroxybutyric acid (GHB).

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption. As a result, 21 CFR 1310.13 provides for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration criteria.

DATES: Written comments must be postmarked and electronic comments sent on or before January 12, 2009.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–222p'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your

comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; *Telephone*: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (21 U.S.C. 801 *et seq.*), as amended. DEA publishes the implementing regulations for this statute in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Illicit Uses of Gamma-Butyrolactone

Gamma-Butyrolactone, or GBL, is a chemical that is used as a precursor in the illicit manufacture of the schedule I controlled substance gamma-hydroxybutyric acid, or GHB. GBL is a necessary and important chemical precursor in the clandestine synthesis of GHB because, to date, no other chemical has been identified as a substitute for GBL in the clandestine process. Congress recognized this and regulated GBL as a List I chemical upon enactment of Public Law 106–172, the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000,'' on February 18, 2000.

The conversion of GBL to GHB in a clandestine laboratory is a simple one-step process. Availability of GBL is the determining factor in producing GHB, not the execution of complicated chemical procedures or having sophisticated scientific equipment. GBL is a unique chemical precursor. It can be either converted into GHB by a simple chemical reaction or efficiently converted into GHB by the body upon ingestion, thus producing the same pharmacological effects as ingesting GHB. For this reason, abusers or predators seeking to use GBL on their victims routinely substitute GBL for GHB in order to obtain the same type of intoxication.

GBL and GHB induce a sense of euphoria and intoxication and are abused for their central nervous system (CNS) depressant effect. An overdose from GBL or GHB may result in respiratory depression, coma, and even death. Both substances have been associated with drug-facilitated sexual assaults. The Drug Abuse Warning Network (DAWN) is a national surveillance system operated by the Substance Abuse and Mental Health Services Administration (SAMHSA), to monitor trends in drug emergency department visits. SAMHSA collects information on GHB and GBL separately but reports GHB and GBL together in its publications. This reflects the similar threat to public safety and abuse liability of GBL to GHB. In sum, the information available from the sources discussed above suggests a similar threat to public safety and abuse liability of GBL to GHB.

Other Regulations That Apply to GBL: Controlled Substance Analogue Provisions

Section 802(32)(B) of Title 21 provides that the designation of GBL, or any other chemical, as a listed chemical does not preclude a finding that the chemical is a controlled substance analogue (21 U.S.C. 802(32)).[1] A controlled substance analogue is treated, for purposes of Federal law, as a schedule I controlled substance to the extent intended for human consumption (21 U.S.C. 813). The analogue provision of the CSA has been applied to prosecute individuals who have diverted GBL for human consumption. Although a chemical commodity when used by legitimate industry, diversion of GBL is tantamount to diversion of a schedule I controlled substance if intended for human consumption.

Concern Over GBL-Containing Chemical Mixtures

Prior to control as a List I chemical, GBL had been sold under false pretenses to disguise its intended use. Suppliers pretended that GBL was being sold for use as ink jet printer cleaners, room deodorizers, and as educational kits (which pretend to demonstrate the scientific principle of an exothermic chemical reaction).

Since the designation of GBL as a List I chemical in 2000, persons who manufacture, distribute, import, or export GBL must be registered with DEA and maintain records of transactions in GBL. These regulatory requirements prevent unscrupulous persons from freely distributing GBL. Persons without a legitimate business need to manufacture or distribute GBL do not receive the required registration from DEA. DEA believes that those wishing to traffic GBL are less willing to purchase GBL from DEA-approved registrants

[1] 21 U.S.C. 802(32)(A) Except as provided in subparagraph (C), the term ''controlled substance analogue'' means a substance—

(i) The chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) With respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a Listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to paragraph (A) of this paragraph that the chemical is a controlled substance analogue.

who are required to maintain records that are accessible to DEA.

DEA has observed the retail marketing and promotion of chemical mixtures containing GBL. Exempt chemical mixtures containing GBL were sold as cosmetic products and contained greater than 99 percent GBL (along with dye(s), fragrance(s), skin conditioners, and other ingredients). DEA became aware that persons were purchasing such products for conversion to GHB, or directly ingesting these products, for their GBL content. Retailers reported that they quickly sold out of these products. DEA notified retailers of the potential for abuse, which resulted in the voluntary withdrawal of these products from store shelves. Manufacturers of said products stated their intent to reformulate.

DEA is concerned that legitimate businesses may be unintentionally contributing to the diversion of GBL. Without regulatory controls, DEA is unable to monitor distributions of such chemical mixtures containing GBL, since registration and recordkeeping requirements do not apply. Regulation of GBL chemical mixtures pursuant to 21 U.S.C. 802(39)(A)(vi) [as amended by Title VII of Pub. L. 109–172] is necessary to reduce the threat to the public health and safety.

Information Gathered by DEA Concerning GBL Chemical Mixtures

On July 19, 2002, DEA published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM) (67 FR 47403; corrected at 67 FR 53842, August 19, 2002; corrected at 67 FR 56776, September 5, 2002) in anticipation of identifying GBL-containing chemical mixtures to exempt by regulation. The ANPRM invited interested persons to submit information related to legitimate formulations containing GBL, including the concentration of GBL in their mixtures.

Defining a Chemical Mixture

Title 21 U.S.C. 802(40) defines the term ''chemical mixture'' as ''a combination of two or more chemical substances, at least one of which is not a List I chemical or a List II chemical, except that such term does not include any combination of a List I chemical or a List II chemical with another chemical that is present solely as an impurity.'' Therefore, a chemical mixture contains any number of listed chemicals in combination with any number of non-listed chemicals.

DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. An inert carrier is any chemical that does not modify the function of the listed chemical but is present to aid in the delivery of the listed chemical. Examples include, but are not limited to, dilutions in water and the presence of a carrier gas. For purposes of control under the CSA, these examples would be controlled as List I or List II chemicals, not as a chemical mixture containing a List I or List II chemical.

Past Regulations Regarding Chemical Mixtures

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100–690) (CDTA) created the legal definition of a ''chemical mixture'' (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory coverage. The CDTA established 21 U.S.C. 802(39)(A)(v) to exclude ''any transaction in a chemical mixture'' from the definition of a ''regulated transaction.'' The result of such exemption was that it provided traffickers with an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

The Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) (DCDCA), enacted in April 1994, subjected all chemical mixtures containing List I and List II chemicals to CSA regulatory requirements, unless such chemical mixtures were specifically exempted by regulation. The regulatory requirements include recordkeeping, reporting, and security for all regulated chemical mixtures with the additional requirement of registration for handlers of List I chemical mixtures. The DCDCA also provided the Attorney General with the authority to establish regulations exempting chemical mixtures from the definition of a ''regulated transaction,'' ''based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered'' (21 U.S.C. 802(39)(A)(vi) as amended by Title VII of Pub. L. 109–172).

DEA treats all chemical mixtures containing List I and List II chemicals as non-regulated (upon the withdrawal of its proposed rule ''Implementation of the Domestic Chemical Diversion Control Act of 1993 (DCDCA)'' (59 FR 51887, October 13, 1994; withdrawn at 59 FR 63738, December 9, 1994)) until it promulgates a final rule that identifies chemical mixtures that are exempt for each List I and List II chemical. The withdrawal sought to prevent the immediate regulation of qualified chemical mixtures, which was not necessary and would impose an undue burden on industry. It also provided DEA the opportunity to gather information to implement regulations pursuant to 21 U.S.C. 802(39)(A)(vi) [as amended by Title VII of Pub. L. 109–172].

In 2003, DEA published a Final Rule (68 FR 23195, May 1, 2003) that identified exempt mixtures containing the chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine, with an effective date of June 2, 2003. In a second Final Rule (69 FR 74957, December 15, 2004; corrected at 70 FR 294, January 4, 2005), DEA promulgated regulations that defined exempt chemical mixtures for 27 of the remaining 38 listed chemicals. The effective date was January 14, 2005. As gamma-butyrolactone was not a listed chemical when DEA initiated this regulatory action in 1998, regulation of chemical mixtures containing gamma-butyrolactone was not addressed but is the subject of this separate regulatory action.

DEA has concluded that some mixtures of GBL are especially prone to diversion. Since the conversion of GBL to GHB is a simple chemical process, DEA is proposing to automatically exempt only those GBL chemical mixtures that meet the exemption criteria specified in 21 U.S.C. 802(39)(A)(vi) as amended by Title VII of Pub. L. 109–172, i.e., those chemical mixtures 1) that are formulated in such a way that the chemical mixture cannot be easily used in the illicit production of a controlled substance and 2) in which the List I or List II chemical cannot be readily recovered.

Comments

DEA received nine responses to the ANPRM, six from industrial firms and three from national associations. In general, the comments expressed a willingness to inform DEA of their formulations to provide assistance in drafting regulations. Most respondents claimed that GBL could not be readily extracted from their chemical mixtures. All respondents stated that good business practices, such as knowing their customer, prevent (limit) diversion. Responses also stated that selling to end-users (non-retail), the high cost of their GBL-containing chemical mixtures, and the customer not having knowledge of the composition, were also deterrents to diversion. The respondents use GBL-

containing chemical mixtures for the following applications: herbicides, automotive coatings, varnishes, electronics, polymers, and other specialty products.

Specifically, two comments stated that GBL is used in chemical mixtures having application to automotive coatings. Because of the low concentration of GBL and the complex composition of these chemical mixtures, DEA agrees with the commenters' statements that these mixtures do not pose a significant risk of diversion. In a Final Rule published in the **Federal Register** on December 15, 2004 (69 FR 74957; corrected at 70 FR 294, January 4, 2005), DEA amended 21 CFR 1310.12 by adding subparagraph 1310.12(d)(2) that defines completely formulated paints and coatings as automatically exempt from CSA regulatory control pertaining to chemicals. This exemption also applies to completely formulated paints and coatings that contain GBL.

In addition, three comments informed DEA that GBL is contained in chemical mixtures used in agricultural chemicals. GBL and other solvent chemicals act as a delivery system for the active ingredient and prevent crystallization. Other chemicals used in these chemical mixtures are emulsifying and defoaming agents. The commenters stated that these chemical mixtures contain up to 20 percent GBL, that the GBL is difficult to extract, and that these chemical mixtures are toxic.

Four comments notified DEA that some chemical mixtures have application in the semiconductor industry contain GBL. In general, these chemical mixtures are used to form films and/or for the processing and cleaning of these films and associated equipment. Commenters indicated that the concentration of GBL ranges from a few percent to approximately 90 percent. From a review of the comments, DEA concludes that the majority of these chemical mixtures are film forming. DEA notes that 21 CFR 1310.12(d)(2) automatically exempts from CSA regulatory control completely formulated paints and coatings and includes these types of film-forming chemical mixtures. This exemption is based on the codified definition of completely formulated paints and coatings in 21 CFR 1310.12(d)(2) that includes a ''functional adherent film.'' In an effort to further clarify that these film forming agents are automatically exempt from CSA chemical regulatory controls, DEA is proposing that 21 CFR 1310.12(d)(2) be revised to state that, ''Included in this category are clear coats, top-coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents.''

One of the aforementioned commenters had concerns about small amounts of GBL in discarded waste streams and informed DEA that these waste materials should be exempt. DEA has finalized regulations (69 FR 74957, December 15, 2004; corrected at 70 FR 294, January 4, 2005) that exempt ''chemical mixtures that are distributed directly to an incinerator for destruction or authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700–22'' (21 CFR 1310.12(d)(1)).

Finally, DEA was informed that some foods and food flavorings contain GBL in minute amounts that are measured in parts per million (ppm). In 1972, an expert panel of the Flavor and Extract Manufacturers Association of the United States concluded that these levels of GBL to be Generally Recognized as Safe (GRAS) as flavoring agents. The commenter informed DEA that typical concentrations are extremely small and less than 22 ppm. DEA recognizes that foods and flavorings that contain GBL levels in the ppm concentration range are GRAS and that such food items have no pharmacological activity.

Food flavorings are chemical mixtures, and if above concentration limits, these mixtures are subject to CSA regulatory controls and provisions. GBL can be treated as a schedule I controlled substance analogue if intended for human consumption. However, currently marketed food flavorings that contain GBL and are GRAS are very unlikely to lead to criminal prosecution as schedule I controlled substance analogues. This is based on (1) Food flavorings being concentrates and consumed only after addition to a food item and not meant to be consumed in the concentrated form, (2) the food flavoring lacks abuse potential because the low concentration of GBL (i.e., ppm concentrations) does not produce pharmacological activity, and (3) treatment of GBL use in food flavorings as GRAS had been in effect prior to placement of GBL in the CSA with no threat to public safety. However, persons who divert food flavorings that contain GBL above the GRAS ppm concentrations for the purposes of manufacturing a controlled substance in violation of the CSA or for human consumption are subject to prosecution. Also, knowing or intentional distribution of GBL or GBL mixtures, regardless of concentration, to persons for the purpose of abuse is subject to prosecution.

Defining Exempt Chemical Mixtures Containing GBL

In defining exempt chemical mixtures containing GBL for purposes of this proposed rule, the clandestine use of GBL and the requirements of 21 U.S.C. 802(39)(A)(vi) were heavily considered. The requirements described by statute do not allow for exemptions based on such factors as: (1) Manufacturers selling only to known customers, (2) the cost of the mixture, (3) the customer's knowledge of the product's chemical content, packaging, and/or such related topics. 21 U.S.C. 802(39)(A)(vi) requires DEA to establish an exemption based on the finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered.

After examination of the comments on the ANPRM and after weighing the risk of diversion, DEA is proposing a 70 percent concentration limit (by weight or volume) to identify GBL chemical mixtures that do not pose a significant risk of diversion. The comments on the ANPRM suggest that some companies' formulations are no more than 70 percent GBL. DEA anticipates that chemical mixtures over 70 percent, as identified for use as protective coatings and films, will be automatically exempt pursuant to 21 CFR 1310.12(d)(2). Other chemical mixtures identified in the comments having concentrations of GBL over 70 percent may qualify for exemption via the application process (21 CFR 1310.13). DEA is proposing a 70 percent concentration limit in an effort to prevent the automatic exemption of chemical mixtures with higher concentration limits such as solvent-based mixtures (e.g., cleaners or thinners). DEA has concluded that these products could be useful to traffickers.

Thresholds and Excluded Transactions for Regulated GBL Chemical Mixtures

GBL, a List I chemical described in 21 CFR 1310.04(g)(1), does not have a threshold. Therefore, all transactions in regulated GBL chemical mixtures are regulated transactions. Certain transactions, described in 21 CFR 1310.08, are excluded from the definition of a regulated transaction. These are domestic, import, and export distributions of GBL weighing 4,000 kilograms (net weight) or more in a single container. This exclusion also applies to chemical mixtures.

Requirements That Apply to Regulated List I Chemical Mixtures

Persons interested in handling chemical mixtures containing List I chemicals (here referred to as regulated chemical mixtures) must comply with the following:

Registration. Any person who manufactures, distributes, imports or exports a regulated chemical mixture, or proposes to engage in the manufacture, distribution, importation or exportation of a regulated chemical mixture, shall obtain a registration pursuant to the CSA (21 U.S.C. 822 and 958). Regulations describing registration for List I chemical handlers are set forth in 21 CFR Part 1309.

A separate registration is required for manufacturing, distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, import, or export of regulated chemical mixtures. DEA recognizes, however, that it is not possible for persons who manufacture, distribute, import, or export GBL-containing regulated chemical mixtures to immediately complete and submit an application for registration and for DEA to issue registrations immediately for those activities. In order to allow continued legitimate commerce in GBL-containing regulated chemical mixtures, DEA is proposing to establish in 21 CFR 1310.09(i) a temporary exemption from the registration requirement for persons desiring to manufacture, distribute, import, or export GBL-containing regulated chemical mixtures, provided that DEA receives a properly completed application for registration on or before 60 days after publication of the Final Rule implementing this Notice of Proposed Rulemaking. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration. The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, remain in effect. Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to GBL-containing regulated chemical mixtures, nor does it supersede state or local laws or regulations. All handlers of regulated chemical mixtures must comply with their state and local requirements in addition to the CSA and other federal regulatory controls.

DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess List I chemicals, if the possession of those chemicals is in the usual course of business (21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B)). For purposes of this exemption, the warehouse must receive the List I chemical from a DEA registrant and shall only distribute the List I chemical back to the DEA registrant and registered location from which it was received. All other activities conducted by a warehouse do not fall under this exemption; a warehouse that distributes List I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register accordingly (21 U.S.C. 802(39)(A)(ii)).

Records and Reports. The CSA (21 U.S.C. 830) requires that certain records be kept and reports be made that involve listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a transaction involving a List I chemical, provided the transaction is a regulated transaction. Because GBL is a listed chemical for which no minimum threshold has been established (21 CFR 1310.04(g)(1)(v)), a distribution, receipt, sale, importation, or exportation of a GBL-containing regulated chemical mixture in any amount, except those very large distributions described in 21 CFR 1310.08(k), is a regulated transaction (21 CFR 1300.02(b)(28)). Title 21 CFR 1310.08(k) exempts domestic, import, and export distributions of GBL weighing 4,000 kilograms (net weight) or more in a single container from the definition of regulated transaction. This exemption also applies to its chemical mixtures. The net weight of the mixture is determined by measuring the mass of the mixture, not the mass of the GBL contained in the mixture.

Further, 21 CFR 1310.05(a) requires that each regulated person shall report to DEA (1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA; (2) any proposed regulated transaction with a person whose description or other identifying characteristics the Administration has previously furnished to the regulated person; (3) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier; and (4) any domestic regulated transaction in a tableting or encapsulating machine.

Import/Export. All imports/exports of a regulated chemical mixture shall comply with the CSA (21 U.S.C. 957 and 971). Regulations for importation and exportation of List I chemicals are found in 21 CFR Part 1313. Separate registration is necessary for each activity (21 CFR 1309.22).

Administrative Inspection. Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of regulated chemical mixtures or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316 Subpart A.

Regulatory Certifications

Regulatory Flexibility and Small Business Concerns

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to determine whether a proposed rule will have a significant economic impact upon a substantial number of small entities. The proposed rule would impose no new requirements on manufacturers, distributors, importers, and exporters that are already registered to handle GBL. DEA has not been able to identify any United States firm that handles high purity GBL mixtures that would be subject to the rule. Therefore, the proposed rule would not affect a substantial number of small entities.

In addition, the requirements of the rule other than the registration fee can be met with standard business records, that is, with orders, invoices, shipping papers, etc. that the business creates and maintains in the normal course of business. The registration fee is $2,293 for manufacturers, and $1,147 for distributors, importers, and exporters. DEA registration and reregistration application fees are established by rulemaking in accordance with DEA statutory mandates (21 U.S.C. 886a). The sectors that could be affected by this rule are organic chemical manufacturers (NAICS 325199) and chemical wholesalers (NAICS 42469); importers and exporters could be either manufacturers or wholesalers. The smallest firms (those with fewer than five employees) in the organic chemical manufacturing and chemical wholesale sector have annual shipments and sales of about $1.27 million and $1.05 million, respectively, based on the 2002

Economic Census, updated to 2007 dollars. The registration fee would represent 0.2 percent of a small chemical manufacturer's shipments and 0.1 percent of a wholesaler's sales. Consequently, even if a United States-based small entity exists that markets high purity GBL mixtures, the rule would not impose a significant economic burden.

In accordance with the Regulatory Flexibility Act, the Acting Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. It has been determined that this rule is a ''significant regulatory action'' under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

As noted in the previous section, DEA is unaware of any United States firm that will have to register as a manufacturer, distributor, importer, or exporter of a GBL mixture. Most commercial mixtures that may exceed the 70 percent concentration are coatings and films, which are already exempt. The only mixtures that DEA has been able to identify that will be covered are essentially pure GBL (99.6–99.9 percent) being sold as paint strippers and cleaners in Europe. Anyone wanting to import these products would be required to register, but DEA considers it unlikely that anyone with a legitimate need for a paint stripper or cleaner would pay the high prices ($120 to $160 per liter) when substitute products are readily available in the U.S. for a fraction of the cost. DEA recognizes that there may be products of which it is not aware that could be subject to the rule and seeks comments on that subject. DEA also notes that any mixture that is more than 70 percent GBL by weight or volume may qualify for an exemption if GBL cannot be readily recovered from the mixture and the mixture cannot be easily used to produce controlled substances.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

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 $120,000,000 or more (adjusted for inflation) in any one year, and 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.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost 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.

Paperwork Reduction Act

Persons manufacturing, distributing, importing and exporting chemical mixtures containing a List I chemical are required to register with DEA. This rule proposes that chemical mixtures regulated due to the presence of GBL are automatically exempt if the concentration of GBL is 70 percent or less by weight or volume. Under this proposed method of automatic exemption, persons who handle chemical mixtures with concentration levels of GBL of 70 percent or less will not be subject to CSA regulatory controls, including the requirement to register with DEA. For persons handling chemical mixtures containing GBL in concentration levels of greater than 70 percent, DEA anticipates granting some of these mixtures exempt status by the application process (21 CFR 1310.13). Therefore, although DEA believes the impact of this rulemaking under the Paperwork Reduction Act will be minimal, at this time it is not feasible for DEA to determine the extent of the impact of this rulemaking on the regulated industry. Once DEA has determined the impact, it will make the necessary filing with the Office of Management and Budget to adjust the burden for its information collection ''application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993'' [OMB control number 1117–0031] for the affected industry.

List of Subjects in 21 CFR Part 1310

Drug traffic control, List I and List II chemicals, reporting requirements.

For the reasons set out above, 21 CFR Part 1310 is proposed to be amended as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. Section 1310.09 is amended by adding new paragraph (k) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(k) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated GBL-containing chemical mixtures, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before [60 days from date of publication of the Final Rule implementing this Notice of Proposed Rulemaking]. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

3. Section 1310.12 is amended in the Table of Concentration Limits in paragraph (c) by adding an entry for gamma-butyrolactone in alphabetical order between ''Ethylamine and its salts'' and ''Hydriodic acid'' under List I chemicals and by revising paragraph (d)(2) to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA Chemical Code No.	Concentration (percent)	Special Conditions
List I Chemicals			
* * *	*	*	* *
Gamma-Butyrolactone	2011	70% by weight or volume.	
* * *	*	*	* *

* * * * *

(d) * * *

(2) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all the component of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, top-coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents.

Dated: October 31, 2008.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. E8–26606 Filed 11–10–08; 8:45 am]

BILLING CODE 4410–09–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51, 54, 61, and 69

[WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45; FCC 08–262]

Universal Service Contribution Methodology; High-Cost Universal Service Support; IP-Enabled Services; Lifeline and Link Up; Developing a Unified Intercarrier Compensation Regime; Numbering Resource Optimization; Intercarrier Compensation for ISP-Bound Traffic; Implementation of the Local Competition Provisions in the Telecommunications Act of 1996; Federal-State Joint Board on Universal Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on three specific proposals that are available in the appendices of the document. We note that members of industry, Congress, and the general public have urged the Commission to seek comment on these proposals. We also seek particular comment on two questions. First, should the additional cost standard utilized under section 252(d)(2) of the Act be either the existing TELRIC standard or the incremental cost standard described in the draft order? Second, should the terminating rate for all section 251(b)(5) traffic be set as either a single, statewide rate or a single rate per operating company?

DATES: Comments are due on or before November 26, 2008 and reply comments are due on or before December 3, 2008.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail: ecfs@fcc.gov,* and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response. Include the docket number in the subject line of the message.
- *Mail:* Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 205544.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jennifer McKee, Telecommunications Access Policy Division, Wireline Competition Bureau, 202–418–7400 or TTY: 202–418–0484 (universal service), or Victoria Goldberg, Pricing Policy Division, Wireline Competition Bureau, 202–418–1520 or TTY 202–418–0484 (intercarrier compensation).

SUPPLEMENTARY INFORMATION: In this Further Notice of Proposed Rulemaking (FNPRM), the Commission seeks comment on three specific proposals. *See Universal Service Contribution Methodology; High-Cost Universal Service Support; IP-Enabled Services; Lifeline and Link Up; Developing a Unified Intercarrier Compensation Regime; Numbering Resource Optimization; Intercarrier Compensation for ISP-Bound Traffic; Implementation of the Local Competition Provisions in the Telecommunications Act of 1996; of Federal-State Joint Board on Universal Service,* WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45, Order on Remand and Report and Order and Further Notice of Proposed Rulemaking, FCC 08–262 (rel. Nov. 5, 2008) (*Order on Remand and Report and Order and Further Notice of Proposed Rulemaking*). Copies of the *Order on Remand and Report and Order and Further Notice of Proposed Rulemaking* and any subsequently filed documents in this matter are or will be available on the Commission's Internet site at *http://www.fcc.gov* and for public inspection Monday through Thursday from 8 a.m. to 4:30 p.m. and Friday from 8 a.m. to 11:30 a.m. at the FCC Reference Information Center, Portals II, 445 12th St., SW., Room CY–A257, Washington, DC 20554. Copies of any such documents may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554, telephone (202) 488–5300, facsimile (202) 488–5563, TTY (202) 488–55672, e-mail

fcc@bcpiweb.com. Accessible formats (computer diskettes, large print, audio recording and Braille) are available to persons with disabilities by contacting the Consumer & Governmental Affairs Bureau, at (202) 418–0531, TTY (202) 418–7365, or at *fcc504@fcc.gov.*

Background

In enacting the Act, Congress sought to introduce competition into local telephone service, which traditionally was provided through regulated monopolies. Recognizing that in introducing such competition, it was threatening the implicit subsidy system that had traditionally supported universal service, it directed the Commission to reform its universal service program to make support explicit and sustainable in the face of developing competition.

The communications landscape has undergone many fundamental changes that were scarcely anticipated when the 1996 Act was adopted. The Internet was only briefly mentioned in the 1996 Act, but now has come into widespread use, with broadband Internet access service increasingly viewed as a necessity. Consistent with this trend, carriers are converting from circuit-switched networks to IP-based networks. These changes have benefited consumers and should be encouraged. Competition has resulted in dramatically lower prices for telephone service, and the introduction of innovative broadband products and services has fundamentally changed the way we communicate, work, and obtain our education, news, and entertainment. At the same time, however, these developments have challenged the outdated regulatory assumptions underlying our universal service and intercarrier compensation regimes, forcing us to reassess our existing approaches. We have seen unprecedented growth in the universal service fund, driven in significant part by increased support for competitive eligible telecommunications carriers. The growth of competition also has eroded the universal service contribution base as the prices for interstate and international services have dropped. Finally, we have seen numerous competitors exploit arbitrage opportunities created by a patchwork of above-cost intercarrier compensation rates.

This is a summary of the FNPRM portion of the *Order on Remand and Report and Order and Further Notice of Proposed Rulemaking.* We seek comment on three appendices not available in this **Federal Register** summary but available on the Commission's Web site at: *http://www.fcc.gov/fcc08262/FCC–08–262A1.pdf.*

The first proposal we seek comment on, attached as Appendix A to the item, is the Chairman's Draft Proposal circulated to the Commission on October 15, 2008, which was placed on the Commission's agenda for a vote on November 4, 2008. This item was subsequently removed from the Agenda on November 3, 2008. The second, attached as Appendix B to the item, is a Narrow Universal Service Reform Proposal circulated to the Commission on October 31, 2008. The third, attached as Appendix C to the item, is a draft Alternative Proposal first circulated by the Chairman on the evening of November 5, 2008. Appendix C incorporates changes proposed in the ex parte presentations attached as Appendix D to the item. We note that members of industry, Congress, and the general public have urged the Commission to seek comment on these proposals.

We seek particular comment on two questions. First, should the additional cost standard utilized under section 252(d)(2) of the Act be either the existing TELRIC standard or the incremental cost standard described in the draft order? Second, should the terminating rate for all section 251(b)(5) traffic be set as either a single, statewide rate or a single rate per operating company?

Comment Filing Procedures

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR sections 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS); (2) the Federal Government's eRulemaking Portal; or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Filers should follow the instructions provided on the Web site for submitting comments.
- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov,* and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.
- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Ex Parte Requirements

This matter shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. *See* 47 CFR 1.1200, 1,1206. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and

arguments presented generally is required. See 47 CFR 1.1206(b). Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in section 1.1206(b) of the Commission's rules. 47 CFR 1.1206(b).

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this FNPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the FNPRM. The Commission will send a copy of the FNPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). *See* 5 U.S.C. 603(a). In addition, the FNPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Proposed Rules

Today, the Commission adopts an FNPRM to seek comment on three specific proposals. The first proposal we seek comment on, attached as Appendix A to the item, is the Chairman's Draft Proposal circulated to the Commission on October 15, 2008, which was placed on the Commission's agenda for a vote on November 4, 2008. This item was subsequently removed from the Agenda on November 3, 2008. The second, attached as Appendix B to the item, is a Narrow Universal Service Reform Proposal circulated to the Commission on October 31, 2008. The third, attached as Appendix C to the item, is a draft Alternative Proposal first circulated by the Chairman on the evening of November 5, 2008. Appendix C incorporates changes proposed in the *ex parte* presentations attached as Appendix D to the item. We note that members of industry, Congress, and the general public have urged the Commission to seek comment on these proposals.

We seek particular comment on two questions. First, should the additional cost standard utilized under section 252(d)(2) of the Act be: (i) The existing TELRIC standard; or (ii) the incremental cost standard described in the draft order? Second, should the terminating rate for all section 251(b)(5) traffic be set as: (i) A single, statewide rate; or (ii) a single rate per operating company?

Legal Basis

The legal basis for any action that may be taken pursuant to the FNPRM is contained in sections 1–4, 201–209, 214, 218–220, 224, 251, 252, 254, 303(r), 332, 403, 502, and 503 of the Communications Act of 1934, as amended, and sections 601 and 706 of the Telecommunications Act of 1996, 47 U.S.C. 151–154, 157 nt, 201–209, 214, 218–220, 224, 251, 252, 254, 303(r), 332, 403, 502, 503, and sections 1.1, 1.411–1.429, and 1.1200–1.1216 of the Commission's rules, 47 CFR 1.1, 1.411–1.429, 1.1200–1.1216

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. 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).

Wired Telecommunications Carriers. The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. According to Census Bureau data for 2002, there were 2,432 firms in this category, total, that operated for the entire year. Of this total, 2,395 firms had employment of 999 or fewer employees, and an additional 37 firms had employment of 1,000 employees or more. Thus, under this size standard, the majority of firms can be considered small.

Local Exchange Carriers (LECs). Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,311 carriers reported that they were incumbent local exchange service providers. Of these 1,311 carriers, an estimated 1,024 have 1,500 or fewer employees and 287 have more than 1,500 employees. Consequently, the Commission estimates that most providers of local exchange service are small entities that may be affected by the rules and policies proposed in the FNPRM.

Incumbent Local Exchange Carriers (Incumbent LECs). Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to incumbent local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,311 carriers reported that they were engaged in the provision of local exchange services. Of these 1,307 carriers, an estimated 1,024 have 1,500 or fewer employees and 287 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by rules adopted pursuant to the FNPRM.

We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,005 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,005 carriers, an estimated 918 have 1,500 or fewer employees and 87 have more than 1,500 employees. In addition, 16

carriers have reported that they are Shared-Tenant Service Providers, and all 16 are estimated to have 1,500 or fewer employees. In addition, 89 carriers have reported that they are Other Local Service Providers. Of the 89, all 89 have 1,500 or fewer employees and none has more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Interexchange Carriers (IXCs). Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to interexchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 300 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of these 300 companies, an estimated 268 have 1,500 or fewer employees and 32 have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Operator Service Providers (OSPs). Neither the Commission nor the SBA has developed a small business size standard specifically for operator service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 28 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 27 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities that may be affected by rules adopted pursuant to the FNPRM.

Payphone Service Providers (PSPs). Neither the Commission nor the SBA has developed a small business size standard specifically for payphone services providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 526 carriers have reported that they are engaged in the provision of payphone services. Of these, an estimated 524 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of payphone service providers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Prepaid Calling Card Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 88 carriers have reported that they are engaged in the provision of prepaid calling cards. Of these, an estimated 85 have 1,500 or fewer employees and three have more than 1,500 employees. Consequently, the Commission estimates that the majority of prepaid calling card providers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Local Resellers. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 151 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 149 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Toll Resellers. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 815 carriers have reported that they are engaged in the provision of toll resale services. Of these, an estimated 787 have 1,500 or fewer employees and 28 have more than 1,500 employees. Consequently, the Commission estimates that the majority of toll resellers are small entities that may be affected by rules adopted pursuant to the FNPRM.

Other Toll Carriers. Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 91 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these 91 companies, an estimated 88 have 1,500 or fewer employees and three have more than 1,500 employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by the rules and policies adopted pursuant to the FNPRM.

800 and 800-Like Service Subscribers. Neither the Commission nor the SBA has developed a small business size standard specifically for 800 and 800-like service (toll free) subscribers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. The most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, 877, and 866 numbers in use. According to our data, at the beginning of December 2007, the number of 800 numbers assigned was 7,860,000; the number of 888 numbers assigned was 5,210,184; the number of 877 numbers assigned was 4,388,682; and the number of 866 numbers assigned was 7,029,116. We do not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small businesses under the SBA size standard. Consequently, we estimate that there are 7,860,000 or fewer small entity 800 subscribers; 5,210,184 or fewer small entity 888 subscribers; 4,388,682 or fewer small entity 877 subscribers; and 7,029,166 or fewer small entity 866 subscribers.

Wireless Carriers and Service Providers

Below, for those services subject to auctions, we note that, as a general matter, the number of winning bidders that qualify as small businesses at the close of an auction does not necessarily represent the number of small businesses currently in service. Also, the Commission does not generally track

subsequent business size unless, in the context of assignments or transfers, unjust enrichment issues are implicated.

Wireless Telecommunications Carriers (except Satellite). Since 2007, the SBA has recognized wireless firms within this new, broad, economic census category. Prior to that time, the SBA had developed a small business size standard for wireless firms within the now-superseded census categories of Paging and Cellular and Other Wireless Telecommunications. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. Because Census Bureau data are not yet available for the new category, we will estimate small business prevalence using the prior categories and associated data. For the first category of Paging, data for 2002 show that there were 807 firms that operated for the entire year. Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more. For the second category of Cellular and Other Wireless Telecommunications, data for 2002 show that there were 1,397 firms that operated for the entire year. Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more. Thus, using the prior categories and the available data, we estimate that the majority of wireless firms can be considered small. According to Commission data, 434 carriers reported that they were engaged in the provision of cellular service, Personal Communications Service (PCS), or Specialized Mobile Radio (SMR) Telephony services, which are placed together in the data. We have estimated that 222 of these are small, under the SBA small business size standard. Thus, under this category and size standard, approximately half of firms can be considered small.

Broadband Personal Communications Service. The broadband personal communications service (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission defined ''small entity'' for Blocks C and F as an entity that has average gross revenues of $40 million or less in the three previous calendar years. For Block F, an additional classification for ''very small business'' was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. These standards defining ''small entity'' in the context of broadband PCS auctions have been approved by the SBA. No small businesses, within the SBA-approved small business size standards bid successfully for licenses in Blocks A and B. There were 90 winning bidders that qualified as small entities in the Block C auctions. A total of 93 small and very small business bidders won approximately 40 percent of the 1,479 licenses for Blocks D, E, and F. On March 23, 1999, the Commission re-auctioned 347 C, D, E, and F Block licenses. There were 48 small business winning bidders. On January 26, 2001, the Commission completed the auction of 422 C and F Broadband PCS licenses in Auction No. 35. Of the 35 winning bidders in that auction, 29 qualified as ''small'' or ''very small'' businesses. Subsequent events, concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant.

Narrowband Personal Communications Services. To date, two auctions of narrowband PCS licenses have been conducted. For purposes of the two auctions that have been held, ''small businesses'' were entities with average gross revenues for the prior three calendar years of $40 million or less. Through these auctions, the Commission has awarded a total of 41 licenses, out of which 11 were obtained by small businesses. To ensure meaningful participation of small business entities in future auctions, the Commission has adopted a two-tiered small business size standard in the *Narrowband PCS Second Report and Order.* A ''small business'' is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $40 million. A ''very small business'' is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $15 million. The SBA has approved these small business size standards. In the future, the Commission will auction 459 licenses to serve Metropolitan Trading Areas (MTAs) and 408 response channel licenses. There is also one megahertz of narrowband PCS spectrum that has been held in reserve and that the Commission has not yet decided to release for licensing. The Commission cannot predict accurately the number of licenses that will be awarded to small entities in future actions. However, four of the 16 winning bidders in the two previous narrowband PCS auctions were small businesses, as that term was defined under the Commission's rules. The Commission assumes, for purposes of this analysis that a large portion of the remaining narrowband PCS licenses will be awarded to small entities. The Commission also assumes that at least some small businesses will acquire narrowband PCS licenses by means of the Commission's partitioning and disaggregation rules.

Paging (Private and Common Carrier). The SBA has developed a small business size standard for Paging, under which a business is small if it has 1,500 or fewer employees. In addition, in the *Paging Third Report and Order*, we developed a small business size standard for ''small businesses'' and ''very small businesses'' for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A ''small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. Additionally, a ''very small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $3 million for the preceding three years. The SBA has approved these small business size standards. According to Commission data, 281 carriers have reported that they are engaged in Paging or Messaging Service. Of these, an estimated 279 have 1,500 or fewer employees, and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of paging providers are small entities that may be affected by our action. An auction of Metropolitan Economic Area licenses commenced on February 24, 2000, and closed on March 2, 2000. Of the 985 licenses auctioned, 440 were sold. Fifty-seven companies claiming small business status won.

Wireless Telephony. Wireless telephony includes cellular, PCS, and specialized mobile radio (SMR) telephony carriers. As noted earlier, the SBA has developed a small business size standard for Cellular and Other Wireless Telecommunications services. Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 434 carriers reported that they were engaged in the provision of wireless telephony. We have estimated that 222 of these are small under the SBA small business size standard.

220 MHz Radio Service—Phase I Licensees. The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees

and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a small business size standard for small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small businesses, we apply the small business size standard under the SBA rules applicable to Cellular and Other Wireless Telecommunications companies. Under this category, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. The Commission estimates that nearly all such licensees are small businesses under the SBA's small business size standard that may be affected by rules adopted pursuant to the FNPRM.

220 MHz Radio Service—Phase II Licensees. The 220 MHz service has both Phase I and Phase II licenses. The Phase II 220 MHz service is a new service, and is subject to spectrum auctions. In the *220 MHz Third Report and Order*, we adopted a small business size standard for ''small'' and ''very small'' businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. This small business size standard indicates that a ''small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. A ''very small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues that do not exceed $3 million for the preceding three years. The SBA has approved these small business size standards. Auctions of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. In the first auction, 908 licenses were auctioned in three different-sized geographic areas: Three nationwide licenses, 30 Regional Economic Area Group (EAG) Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Thirty-nine small businesses won licenses in the first 220 MHz auction. The second auction included 225 licenses: 216 EA licenses and 9 EAG licenses. Fourteen companies claiming small business status won 158 licenses.

800 MHz and 900 MHz Specialized Mobile Radio Licenses. The Commission awards ''small entity'' and ''very small entity'' bidding credits in auctions for Specialized Mobile Radio (SMR) geographic area licenses in the 800 MHz and 900 MHz bands to firms that had revenues of no more than $15 million in each of the three previous calendar years, or that had revenues of no more than $3 million in each of the previous calendar years, respectively. These bidding credits apply to SMR providers in the 800 MHz and 900 MHz bands that either hold geographic area licenses or have obtained extended implementation authorizations. The Commission does not know how many firms provide 800 MHz or 900 MHz geographic area SMR service pursuant to extended implementation authorizations, nor how many of these providers have annual revenues of no more than $15 million. One firm has over $15 million in revenues. The Commission assumes, for purposes here, that all of the remaining existing extended implementation authorizations are held by small entities, as that term is defined by the SBA. The Commission has held auctions for geographic area licenses in the 800 MHz and 900 MHz SMR bands. There were 60 winning bidders that qualified as small or very small entities in the 900 MHz SMR auctions. Of the 1,020 licenses won in the 900 MHz auction, bidders qualifying as small or very small entities won 263 licenses. In the 800 MHz auction, 38 of the 524 licenses won were won by small and very small entities.

700 MHz Guard Band Licensees. In the *700 MHz Guard Band Order*, we adopted a small business size standard for ''small businesses'' and ''very small businesses'' for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A ''small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $40 million for the preceding three years. Additionally, a ''very small business'' is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $15 million for the preceding three years. An auction of 52 Major Economic Area (MEA) licenses commenced on September 6, 2000, and closed on September 21, 2000. Of the 104 licenses auctioned, 96 licenses were sold to nine bidders. Five of these bidders were small businesses that won a total of 26 licenses. A second auction of 700 MHz Guard Band licenses commenced on February 13, 2001 and closed on February 21, 2001. All eight of the licenses auctioned were sold to three bidders. One of these bidders was a small business that won a total of two licenses.

Rural Radiotelephone Service. The Commission has not adopted a size standard for small businesses specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio System (BETRS). The Commission uses the SBA's small business size standard applicable to Cellular and Other Wireless Telecommunications, i.e., an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that there are 1,000 or fewer small entity licensees in the Rural Radiotelephone Service that may be affected by the rules and policies adopted herein.

Air-Ground Radiotelephone Service. The Commission has not adopted a small business size standard specific to the Air-Ground Radiotelephone Service. We will use SBA's small business size standard applicable to Cellular and Other Wireless Telecommunications, i.e., an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and we estimate that almost all of them qualify as small under the SBA small business size standard and may be affected by rules adopted pursuant to the FNPRM.

Aviation and Marine Radio Services. Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Cellular and Other Telecommunications, which is 1,500 or fewer employees. Most applicants for recreational licenses are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, we estimate that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a ''small'' business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $15 million dollars. In addition, a ''very small'' business is one that, together with

controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $3 million dollars. There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as ''small'' businesses under the above special small business size standards and may be affected by rules adopted pursuant to the FNPRM.

Fixed Microwave Services. Fixed microwave services include common carrier, private operational-fixed, and broadcast auxiliary radio services. 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 created a size standard for a small business specifically with respect to fixed microwave services. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Cellular and Other Telecommunications, which is 1,500 or fewer employees. The Commission does not have data specifying the number of these licensees that have more than 1,500 employees, and thus is unable at this time to estimate with greater precision the number of fixed microwave service licensees that would qualify as small business concerns under the SBA's small business size standard. Consequently, the Commission estimates that there are up to 22,015 common carrier fixed licensees and up to 61,670 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services that may be small and may be affected by the rules and policies adopted herein. We note, however, that the common carrier microwave fixed licensee category includes some large entities.

Offshore Radiotelephone Service. This service operates on several UHF television broadcast channels that are not used for television broadcasting in the coastal areas of states bordering the Gulf of Mexico. There are approximately 55 licensees in this service. We are unable to estimate at this time the number of licensees that would qualify as small under the SBA's small business size standard for Cellular and Other Wireless Telecommunications services. Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees.

Wireless Communications Services. This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission established small business size standards for the wireless communications services (WCS) auction. A ''small business'' is an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' is an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these small business size standards. The Commission auctioned geographic area licenses in the WCS service. In the auction, there were seven winning bidders that that qualified as ''very small business'' entities, and one that qualified as a ''small business'' entity. We conclude that the number of geographic area WCS licenses affected by this analysis includes these eight entities.

39 GHz Service. The Commission created a special small business size standard for 39 GHz licenses—an entity that has average gross revenues of $40 million or less in the three previous calendar years. An additional size standard for ''very small business'' is: An entity that, together with affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. The SBA has approved these small business size standards. The auction of the 2,173 39 GHz licenses began on April 12, 2000, and closed on May 8, 2000. The 18 bidders who claimed small business status won 849 licenses. Consequently, the Commission estimates that 18 or fewer 39 GHz licensees are small entities that may be affected by rules adopted pursuant to the FNPRM.

Wireless Cable Systems. Wireless cable systems use 2 GHz band frequencies of the Broadband Radio Service (BRS), formerly Multipoint Distribution Service (MDS), and the Educational Broadband Service (EBS), formerly Instructional Television Fixed Service (ITFS), to transmit video programming and provide broadband services to residential subscribers. These services were originally designed for the delivery of multichannel video programming, similar to that of traditional cable systems, but over the past several years licensees have focused their operations instead on providing two-way high-speed Internet access services. We estimate that the number of wireless cable subscribers is approximately 100,000, as of March 2005. Local Multipoint Distribution Service (LMDS) is a fixed broadband point-to-multipoint microwave service that provides for two-way video telecommunications. As described below, the SBA small business size standard for the broad census category of Cable and Other Program Distribution, which consists of such entities generating $13.5 million or less in annual receipts, appears applicable to MDS, ITFS and LMDS.

The Commission has defined small MDS (now BRS) and LMDS entities in the context of Commission license auctions. In the 1996 MDS auction, the Commission defined a small business as an entity that had annual average gross revenues of less than $40 million in the previous three calendar years. This definition of a small entity in the context of MDS auctions has been approved by the SBA. In the MDS auction, 67 bidders won 493 licenses. Of the 67 auction winners, 61 claimed small business status. At this time, the Commission estimates 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 have gross revenues that are not more than $40 million and are thus considered small entities. MDS licensees and wireless cable operators that did not receive their licenses as a result of the MDS auction fall under the SBA small business size standard for Cable and Other Program Distribution. Information available to us indicates that there are approximately 850 of these licensees and operators that do not generate revenue in excess of $13.5 million annually. Therefore, we estimate that there are approximately 850 small entity MDS (or BRS) providers, as defined by the SBA and the Commission's auction rules that may be affected by rules adopted pursuant to the FNPRM.

Educational institutions are included in this analysis as small entities; however, the Commission has not created a specific small business size standard for ITFS (now EBS). We estimate that there are currently 2,032 ITFS (or EBS) licensees, and all but 100 of the licenses are held by educational institutions. Thus, we estimate that at least 1,932 ITFS licensees are small entities that may be affected by rules adopted pursuant to the FNPRM.

In the 1998 and 1999 LMDS auctions, the Commission defined a small business as an entity that has annual average gross revenues of less than $40 million in the previous three calendar years. Moreover, the Commission added an additional classification for a ''very small business,'' which was defined as an entity that had annual average gross revenues of less than $15 million in the previous three calendar years. These definitions of ''small business'' and ''very small business'' in the context of the LMDS auctions have been approved

by the SBA. In the first LMDS auction, 104 bidders won 864 licenses. Of the 104 auction winners, 93 claimed status as small or very small businesses. In the LMDS re-auction, 40 bidders won 161 licenses. Based on this information, we believe that the number of small LMDS licenses will include the 93 winning bidders in the first auction and the 40 winning bidders in the re-auction, for a total of 133 small entity LMDS providers as defined by the SBA and the Commission's auction rules.

218–219 MHz Service. The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, the small business size standard was an entity that, together with its affiliates, has no more than a $6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than $2 million in annual profits each year for the previous two years. In the *218–219 MHz Report and Order and Memorandum Opinion and Order*, we established a small business size standard for a ''small business'' as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and their affiliates, has average annual gross revenues not to exceed $15 million for the preceding three years. A ''very small business'' is defined as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and its affiliates, has average annual gross revenues not to exceed $3 million for the preceding three years. These size standards will be used in future auctions of 218–219 MHz spectrum.

24 GHz—Incumbent Licensees. This analysis may affect incumbent licensees who were relocated to the 24 GHz band from the 18 GHz band, and applicants who wish to provide services in the 24 GHz band. The applicable SBA small business size standard is that of ''Cellular and Other Wireless Telecommunications'' companies. This category provides that such a company is small if it employs no more than 1,500 persons. We believe that there are only two licensees in the 24 GHz band that were relocated from the 18 GHz band, Teligent and TRW, Inc. It is our understanding that Teligent and its related companies have less than 1,500 employees, though this may change in the future. TRW is not a small entity. Thus, only one incumbent licensee in the 24 GHz band is a small business entity.

24 GHz—Future Licensees. With respect to new applicants in the 24 GHz band, the size standard for ''small business'' is an entity that, together with controlling interests and affiliates, has average annual gross revenues for the three preceding years not in excess of $15 million. ''Very small business'' in the 24 GHz band is an entity that, together with controlling interests and affiliates, has average gross revenues not exceeding $3 million for the preceding three years. The SBA has approved these small business size standards. These size standards will apply to a future 24 GHz license auction, if held.

Satellite Service Providers

Satellite Telecommunications. Since 2007, the SBA has recognized satellite firms within this revised category, with a small business size standard of $15 million. The most current Census Bureau data, however, are from the (last) economic census of 2002, and we will use those figures to gauge the prevalence of small businesses in this category. Those size standards are for the two census categories of ''Satellite Telecommunications'' and ''Other Telecommunications.'' Under both prior categories, such a business was considered small if it had, as now, $15 million or less in average annual receipts.

The first category of Satellite Telecommunications ''comprises establishments primarily engaged in providing point-to-point telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' For this category, Census Bureau data for 2002 show that there were a total of 371 firms that operated for the entire year. Of this total, 307 firms had annual receipts of under $10 million, and 26 firms had receipts of $10 million to $24,999,999. Consequently, we estimate that the majority of Satellite Telecommunications firms are small entities that might be affected by rules adopted pursuant to the FNPRM.

The second category of Other Telecommunications ''comprises establishments primarily engaged in: (1) Providing specialized telecommunications applications, such as satellite tracking, communications telemetry, and radar station operations; or (2) providing satellite terminal stations and associated facilities operationally connected with one or more terrestrial communications systems and capable of transmitting telecommunications to or receiving telecommunications from satellite systems.'' For this category, Census Bureau data for 2002 show that there were a total of 332 firms that operated for the entire year. Of this total, 303 firms had annual receipts of under $10 million and 15 firms had annual receipts of $10 million to $24,999,999. Consequently, we estimate that the majority of Other Telecommunications firms are small entities that might be affected by our action.

Cable and OVS Operators

In 2007, the SBA recognized new census categories for small cable entities. However, there are no census data yet in existence that may be used to calculate the number of small entities that fit these definitions. Therefore, we will use prior definitions of these types of entities in order to estimate numbers of potentially-affected small business entities.

Cable and Other Program Distribution. The Census Bureau defines this category as ''third-party distribution systems for broadcast programming * * * [that] deliver visual, aural, or textual programming received from cable networks, local television stations, or radio networks to consumers via cable or direct-to-home satellite systems on a subscription or fee basis * * * [and] do not generally originate programming material.'' The SBA has developed a small business size standard for Cable and Other Program Distribution, of firms having $13.5 million or less in annual receipts. According to Census Bureau data for 2002, there were a total of 1,191 firms in this category that operated for the entire year. Of this total, 1,087 firms had annual receipts of under $10 million, and 43 firms had receipts of $10 million or more but less than $25 million. Thus, under this size standard, the majority of firms can be considered small and may be affected by rules adopted pursuant to the FNPRM.

Cable Companies and Systems. The Commission has developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers, nationwide. Industry data indicate that, of 1,076 cable operators nationwide, all but eleven are small under this size standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 7,208 systems nationwide, 6,139 systems have under 10,000 subscribers, and an additional 379 systems have 10,000–

19,999 subscribers. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the FNPRM.

Cable System Operators. The Act also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Industry data indicate that, of 1,076 cable operators nationwide, all but ten are small under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

Open Video Services. Open Video Service (OVS) systems provide subscription services. As noted above, the SBA has created a small business size standard for Cable and Other Program Distribution. This standard provides that a small entity is one with $13.5 million or less in annual receipts. The Commission has certified approximately 45 OVS operators to serve 75 areas, and some of these are currently providing service. Affiliates of Residential Communications Network, Inc. (RCN) received approval to operate OVS systems in New York City, Boston, Washington, DC, and other areas. RCN has sufficient revenues to assure that they do not qualify as a small business entity. Little financial information is available for the other entities that are authorized to provide OVS and are not yet operational. Given that some entities authorized to provide OVS service have not yet begun to generate revenues, the Commission concludes that up to 44 OVS operators (those remaining) might qualify as small businesses that may be affected by rules adopted pursuant to the FNPRM.

Internet Service Providers, Web Portals and Other Information Services

In 2007, the SBA recognized two new small business, economic census categories: (1) Internet Publishing and Broadcasting and Web Search Portals and; (2) All Other Information Services. However, there is no census data yet in existence that may be used to calculate the number of small entities that fit these definitions. Therefore, we will use prior definitions of these types of entities in order to estimate numbers of potentially affected small business entities.

Internet Service Providers. The SBA has developed a small business size standard for Internet Service Providers (ISPs). ISPs ''provide clients access to the Internet and generally provide related services such as Web hosting, Web page designing, and hardware or software consulting related to Internet connectivity.'' Under the SBA size standard, such a business is small if it has average annual receipts of $23 million or less. According to Census Bureau data for 2002, there were 2,529 firms in this category that operated for the entire year. Of these, 2,437 firms had annual receipts of under $10 million, and an additional 47 firms had receipts of between $10 million and $24,999,999. Consequently, we estimate that the majority of these firms are small entities that may be affected by rules adopted pursuant to the FNPRM.

Web Search Portals. Our action may pertain to interconnected VoIP services, which could be provided by entities that provide other services such as e-mail, online gaming, Web browsing, video conferencing, instant messaging, and other, similar IP-enabled services. The Commission has not adopted a size standard for entities that create or provide these types of services or applications. However, the Census Bureau has identified firms that ''operate Web sites that use a search engine to generate and maintain extensive databases of Internet addresses and content in an easily searchable format.'' The SBA has developed a small business size standard for this category of $6.5 million or less in average annual receipts. According to Census Bureau data for 2002, there were 342 firms in this category that operated for the entire year. Of these, 303 had annual receipts of under $5 million, and an additional 15 firms had receipts of between $5 million and $9,999,999. Consequently, we estimate that the majority of these firms are small entities that may be affected by rules adopted pursuant to the FNPRM.

Data Processing, Hosting, and Related Services. Entities in this category ''primarily * * * provid[e] infrastructure for hosting or data processing services.'' The SBA has developed a small business size standard for this category; that size standard is $23 million or less in average annual receipts. According to Census Bureau data for 2002, there were 6,877 firms in this category that operated for the entire year. Of these, 6,418 had annual receipts of under $10 million, and an additional 251 firms had receipts of between $10 million and $24,999,999. Consequently, we estimate that the majority of these firms are small entities that may be affected by rules adopted pursuant to the FNPRM.

All Other Information Services. The Census Bureau defines this industry as including ''establishments primarily engaged in providing other information services (except new syndicates and libraries and archives).'' Our action pertains to interconnected VoIP services, which could be provided by entities that provide other services such as e-mail, online gaming, Web browsing, video conferencing, instant messaging, and other, similar IP-enabled services. The SBA has developed a small business size standard for this category; that size standard is $6.5 million or less in average annual receipts. According to Census Bureau data for 2002, there were 155 firms in this category that operated for the entire year. Of these, 138 had annual receipts of under $5 million, and an additional four firms had receipts of between $5 million and $9,999,999. Consequently, we estimate that the majority of these firms are small entities that may be affected by our action.

Internet Publishing and Broadcasting. The Census Bureau defines this industry as ''establishments engaged in publishing and/or broadcasting content on the Internet exclusively * * *. [that * * *] do not provide traditional (non-Internet) versions of the content that they publish or broadcast.'' The SBA has developed a small business size standard for this Census category; that size standard is 500 or fewer employees. According to Census Bureau data for 2002, there were 1,362 firms in this category that operated for the entire year. Of these, 1,351 had employment of 499 or fewer employees, and 11 firms had employment of between 500 and 999. Consequently, we estimate that the majority of these firms are small entities that may be affected by our action.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

In the FNPRM, the Commission seeks comment on three specific proposals. The first proposal we seek comment on, attached as Appendix A to the item, is the Chairman's Draft Proposal circulated to the Commission on October 15, 2008, which was placed on the Commission's agenda for a vote on November 4, 2008.

This item was subsequently removed from the Agenda on November 3, 2008. The second, attached as Appendix B to the item, is a Narrow Universal Service Reform Proposal circulated to the Commission on October 31, 2008. The third, attached as Appendix C to the item, is a draft Alternative Proposal first circulated by the Chairman on the evening of November 5, 2008. Appendix C incorporates changes proposed in the ex parte presentations attached as Appendix D to the item. We note that members of industry, Congress, and the general public have urged the Commission to seek comment on these proposals.

We seek particular comment on two questions. First, should the additional cost standard utilized under section 252(d)(2) of the Act be either the existing TELRIC standard or the incremental cost standard described in the draft order? Second, should the terminating rate for all section 251(b)(5) traffic be set as either a single, statewide rate or a single rate per operating company?

Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules 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.''

The FNPRM seeks comment from all interested parties. Small entities are encouraged to bring to the Commission's attention any specific concerns they may have with the proposals outlined in the FNPRM.

Throughout these proceedings the Commission has received proposals to treat small entities differently. We believe that consideration of commenters' transition proposals for implementing intercarrier compensation reform, as well as alternatives for a carriers' recovery of intercarrier revenues reduced as a result of any reforms that might be adopted could be consistent with our goals of a unified and simplified intercarrier compensation regime that will reduce arbitrage opportunities and promote innovation and competition and our statutory requirement to secure the viability of universal service.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

Paperwork Reduction Act

This document may contain proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, we seek specific comment on how we might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–26849 Filed 11–7–08; 4:15 pm]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2295; MB Docket No. 08–213; RM–11500]

Television Broadcasting Services; Grand Island, NE

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a channel substitution proposed by Hill Broadcasting Company, Inc. (''Hill''), the permittee of KTVG-DT, post-transition DTV channel 19, Grand Island, Nebraska. Hill requests the substitution of DTV channel 16 for post-transition DTV channel 19 at Grand Island.

DATES: Comments must be filed on or before December 12, 2008, and reply comments on or before December 29, 2008.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: William H. Crispin, Esq., Crispin & Greenberg, P.L.L.C., 555 13th Street, NW., Suite 420 West., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, *adrienne.denysyk@fcc.gov,* Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 08–213, adopted October 10, 2008, and released October 15, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC, 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.62 [Amended]

2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Nebraska, is amended by adding DTV channel 16 and removing DTV channel 19 at Grand Island.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E8–26734 Filed 11–10–08; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AV52

[FWS–R4–ES–2008–0047]

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Louisiana Black Bear

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period, notice of availability of draft economic analysis, and amended required determinations.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on the proposed designation of critical habitat for the Louisiana black bear (*Ursus americanus luteolus*) under the Endangered Species Act of 1973, as amended (Act). We also announce the availability of a draft economic analysis (DEA) and an amended required determinations section of the proposal. We are reopening the comment period to allow all interested parties an opportunity to comment simultaneously on the revised proposed rule, the associated DEA, and the amended required determinations section. If you submitted comments previously, you do not need to resubmit them because we have already incorporated them into the public record and will fully consider them in preparation of the final rule.

DATES: We will consider comments received on or before December 12, 2008.

ADDRESSES: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R4–ES–2008–0047; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the ''Public Comments'' section below for more information).

FOR FURTHER INFORMATION CONTACT: Jim Boggs, Supervisor, U.S. Fish and Wildlife Service, Louisiana Field Office, 646 Cajundome Blvd., Suite 400, Lafayette, LA 70506; telephone: 337–291–3100; facsimile: 337–291–3139. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period on our proposed designation of critical habitat for the Louisiana black bear that was published in the **Federal Register** on May 6, 2008 (73 FR 25354), our draft economic analysis of the proposed designation, and the amended required determinations provided in this document. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) The reasons why we should or should not designate habitat as critical habitat under section 4 of the Act (16 U.S.C. 1531 *et seq.*).

(2) Specific information on:

(a) The distribution of the Louisiana black bear;

(b) The amount and distribution of Louisiana black bear habitat; and

(c) Which habitat contains the features essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Any foreseeable economic, national security, or other relevant impacts that may result from the proposed designation and, in particular, any impacts on small entities, and the benefits of including or excluding areas that exhibit these impacts.

(5) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments;

(6) Whether the benefits of excluding any particular area from critical habitat outweigh the benefits of including that area as critical habitat under section 4(b)(2) of the Act, after considering the potential impacts and benefits of the proposed critical habitat designation, and more specifically, whether U.S. Department of Agriculture (USDA) Wetland Reserve Program permanent easements on privately owned lands provide sufficient protection and management to justify their exclusion from critical habitat on that basis.

(7) Information on the extent to which the description of economic impacts in the DEA is complete and accurate.

(8) The likelihood of adverse social reactions to the designation of critical habitat, as discussed in the DEA, and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed critical habitat designation.

You may submit your comments and materials concerning the proposed rule or DEA by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov*, your entire comment—including any personal identifying information—will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov*.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule and draft economic analysis, will be available for public inspection on *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Louisiana Field Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule and the DEA on the Internet at *http://*

www.regulations.gov at Docket Number FWS–R4–ES–2008–0047, or by mail from the Louisiana Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat. For more information on previous Federal actions concerning the Louisiana black bear, refer to the proposed designation of critical habitat published in the **Federal Register** on May 6, 2008 (73 FR 25354). On December 2, 1993, we proposed critical habitat for the Louisiana black bear (58 FR 63560). That proposal had a 90-day comment period, ending March 2, 1994. We then reopened the public comment period from March 7, 1994 (59 FR 10607) through April 4, 1994. During that reopened comment period, we held a public hearing in New Iberia, Louisiana, on March 23, 1994. On April 1, 1994, we extended the reopened comment period through May 25, 1994, and announced two more public hearings (May 10, 1994, in West Monroe, Louisiana, and May 11, 1994, in New Iberia, Louisiana) (59 FR 15366). We never published a final rule designating critical habitat.

On September 6, 2005, Mr. Harold Schoeffler and Louisiana Crawfish Producers Association-West filed suit in U.S. District Court for the Western District of Louisiana (Civil Action No. CV05–1573 (W.D. La.)) challenging the Service's failure to designate critical habitat for the Louisiana black bear. On June 26, 2007, the District Court ordered the Service to withdraw the December 2, 1993, proposed critical habitat rule and create a new proposed critical habitat designation by no later than 4 months from the date of the judgment and to publish a final designation by no later than 8 months from the date of the proposed or new rule. On September 5, 2007, following a settlement agreement, the Court revised its order to require the Service to: (1) Withdraw the December 2, 1993, proposed rule and submit a prudency determination and, if prudent, a new proposed critical habitat designation to the Office of the Federal Register by April 26, 2008; and (2) submit a final critical habitat determination, if applicable, to the Office of the Federal Register by February 26, 2009. On May 6, 2008, we published our proposed rule to designate critical habitat for the Louisiana black bear (73 FR 25394) in accordance with section 4(b)(2) of the Act. We concurrently withdrew the 1993 proposal and made a new prudency determination. In total, we proposed approximately 1,330,000 acres (538,894 hectares (ha)) of critical habitat located in Avoyelles, East Carroll, Catahoula, Concordia, Franklin, Iberia, Iberville, Madison, Pointe Coupee, Richland, St. Martin, St. Mary, Tensas, West Carroll, and West Feliciana Parishes, Louisiana. For more information on the threatened Louisiana black bear or its habitat, refer to the final listing rule published in the **Federal Register** on January 7, 1992 (57 FR 588), and to our 1995 final recovery plan for the bear, which is available online at *http://www.regulations.gov* (at Docket Number FWS–R4–ES–2008–0047) or from the Louisiana Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

Draft Economic Analysis

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific and commercial data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat. We have prepared a DEA of our May 6, 2008 (73 FR 25354), proposed rule to designate critical habitat for the Louisiana black bear.

The intent of the DEA is to identify and analyze the potential economic impacts associated with the proposed critical habitat designation for the Louisiana black bear. The DEA quantifies the economic impacts of all potential conservation efforts for the Louisiana black bear; some of these costs will likely be incurred regardless of whether we designate critical habitat. The economic impact of the proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.'' The ''without critical habitat'' scenario represents the baseline for the analysis, considering protections already in place for the species (e.g., under the Federal listing and other Federal, State, and local regulations). The baseline, therefore, represents the costs incurred regardless of whether critical habitat is designated. The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts are those not expected to occur absent the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat above and beyond the baseline costs; these are the costs we may consider in the final designation of critical habitat. The analysis looks retrospectively at baseline impacts incurred since the species was listed, and forecasts both baseline and incremental impacts likely to occur if we finalize the proposed critical habitat.

The DEA provides estimated costs of the foreseeable potential economic impacts of the proposed critical habitat designation for the bear over the next 20 years, which was determined to be the appropriate period for analysis because limited planning information was available for most activities to forecast activity levels for projects beyond a 20-year timeframe. It identifies potential incremental costs as a result of the proposed critical habitat designation; these are those costs attributed to critical habitat over and above those baseline costs attributed to listing. The DEA quantifies economic impacts of Louisiana black bear conservation efforts associated with the following categories of activity: (1) Oil and gas exploration and development; (2) species/habitat management; (3) recreational and residential development; (4) agriculture; (5) transportation; and (6) forestry. Due to uncertainty in the amount of oil and gas development over the next 20 years, cost estimates were calculated for a low scenario of oil and gas development (one-third of the historical rate) and a high scenario (continuation of the historical rate).

The pre-designation (1992 to 2008) impacts associated with species conservation activities for the Louisiana black bear in areas proposed as critical habitat are approximately $68.4 to $76.6 million applying a 3 percent discount rate, and $84.9 to $97.0 million applying a 7 percent discount rate. The post-designation (2009 to 2028) baseline impacts (those estimated to occur

regardless of the critical habitat designation) associated with species conservation were estimated to range from $9.0 million to $19.0 million applying a 3 percent discount rate, or $6.7 million to $14 million applying a 7 percent discount rate). Under a low oil and gas development scenario, over 50 percent of post-designation baseline economic impacts are related to species management and 28 percent are related to oil and gas development. Under the high scenario, oil and gas exploration and development accounted for 65 percent of post-designation baseline economic impacts and species management accounted for 25 percent. Development and agriculture related impacts comprise approximately 20 to 11 percent of the impacts, under the low and high scenarios, respectively.

All incremental impacts attributed to the proposed critical habitat designation are expected to be associated with oil and gas activities. The DEA estimates the post-designation incremental economic impacts for the next 20 years to range from $1.5 million to 8.6 million, applying a 3 percent discount rate, or $1.1 million to $6.3 million applying a 7 percent discount rate. The range in values of incremental costs is a result of the uncertainty in forecasting the number of new wells that are likely to be drilled in the next 20 years. Incremental impacts are not anticipated for other activities (including areas considered for exclusion) potentially affected by the critical habitat designation.

Post-designation baseline impacts for areas proposed for exclusion were calculated separately from areas proposed as critical habitat. Those impacts are related to the purchase of Wetlands Reserve Program easements and associated habitat management practices by the USDA Natural Resources Conservation Service, and are estimated to be approximately $98.7, million applying a 3 percent discount rate, and $73.0 million, applying a 7 percent discount rate.

Only the incremental costs that may result from the designation of critical habitat, over and above the costs associated with species protection under the Act more generally, may be considered in designating critical habitat; therefore, the methodology for distinguishing these two categories of costs is important. In the absence of critical habitat, Federal agencies must ensure that any actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered species or threatened species—costs associated with such actions are considered baseline costs. Once an area is designated as critical habitat, proposed actions that have a Federal nexus in this area also will require consultation and potential modification to ensure that the action does not result in the destruction or adverse modification of designated critical habitat—costs associated with these actions are considered incremental costs. Incremental consultation that takes place as a result of critical habitat designation may fall into one of three categories: (1) Additional effort to address adverse modification in a new consultation; (2) re-initiation of consultation to address effects to critical habitat; and (3) incremental consultation resulting entirely from critical habitat designation (i.e., where a proposed action may affect unoccupied critical habitat). However, because no unoccupied habitat is being proposed for designation, no consultations in category 3 are projected.

As stated earlier, we are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rule and our amended required determinations. We may revise the proposed rule or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusions will not result in the extinction of this species.

Required Determinations—Amended

In our May 6, 2008, proposed rule (73 FR 25354), we indicated that we would defer our determination of compliance with several statutes and Executive Orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA data in making these determinations. In this document, we affirm the information in our proposed rule concerning Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 12630 (Takings), E.O. 13132 (Federalism), E.O. 12988 (Civil Justice Reform), E.O. 13211 (Energy, Supply, Distribution, and Use), the Unfunded Mandates Reform Act, the Paperwork Reduction Act, the National Environmental Policy Act, and the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951). However, based on the DEA data, we revise our required determination concerning the Regulatory Flexibility Act.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of our final rule making.

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations, and small governmental jurisdictions including school boards and city and town governments that serve fewer than 50,000 residents, as well as small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the proposed designation of critical habitat for the Louisiana black bear would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities, such as oil and gas

exploration and development, species management, residential development, forestry, agriculture, and transportation. In order to determine whether it is appropriate for our agency to certify that this rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat affects activities conducted, funded, permitted, or authorized by Federal agencies.

If we finalize this proposed critical habitat designation, Federal agencies must consult with us under section 7 of the Act if their activities may affect designated critical habitat. Consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In the DEA, we evaluated the potential economic effects on small entities resulting from implementation of conservation actions related to the proposed designation of critical habitat for the Louisiana black bear. Based on that analysis, only small business entities that rely on oil and gas exploration and development were identified as entities that could be affected by the incremental impacts from the proposed rule. Impacts described in Appendix A of the DEA are predominantly associated with crude petroleum and natural gas extraction; liquid natural gas exploration; and oil and gas well drilling activities in areas proposed for final critical habitat for the Louisiana black bear. These impacts would be expected to be borne by 45 small businesses that operate in the oil and gas exploration and development industry at the time of final critical habitat designation. The average cost to a small business over the next 20 years is estimated to range from $25,000 to $141,000, discounted at 7 percent. Please refer to our Draft Economic Analysis of the proposed critical habitat designation for a more detailed discussion of potential economic impacts.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. We have identified 45 small entities that may be impacted by the proposed critical habitat designation. For the above reasons and based on currently available information, we certify that if promulgated, the proposed designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Authors

The primary authors of this notice are the staff members of the Louisiana Field Office, Southeast Region, U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: October 30, 2008.

Lyle Laverty,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–26733 Filed 11–10–08; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 73, No. 219
Wednesday, November 12, 2008

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.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will meet on Friday, November 14, 2008. The meeting will be held in the Caucus Room of the Russell Senate Office Building, 1st and Constitution Avenues, NE., Washington, DC at 9 a.m.

The ACHP was established by the National Historic Preservation Act of 1966 (16 U.S.C. 470 *et seq.*) to advise the President and Congress on national historic preservation policy and to comment upon Federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for inclusion in the National Register of Historic Places. The ACHP's members are the Architect of the Capitol; the Secretaries of the Interior, Agriculture, Defense, Housing and Urban Development, Commerce, Education, Veterans Affairs, and Transportation; the Administrator of the General Services Administration; the Chairman of the National Trust for Historic Preservation; the President of the National Conference of State Historic Preservation Officers; a Governor; a Mayor; a Native American; and eight non-Federal members appointed by the President.

The agenda for the meeting includes the following:

Call To Order—9 a.m.

I. Chairman's Welcome
II. Preserve America Award Presentation
III. Native American Activities
  A. Native American Advisory Group
  B. Native American Program Report
IV. Preserve America Program Implementation
  A. Preserve America Stewards Initiative
  B. Preserve America Communities and Grants
  C. Preserve America Summit Implementation
  D. Preserve America/Save America's Treasures Authorizing Legislation
V. Transition Planning
  A. Development of ACHP Transition Plan
  B. Sustainability and Historic Preservation in the New Administration
VI. Preservation Initiatives Committee
  A. Legislative Update
  B. Economic Benefits of Preservation Study
VII. Federal Agency Programs Committee
  A. National Park Service Programmatic Agreement
  B. Bureau of Land Management Nationwide Programmatic Agreement
  C. Department of Defense Program Comments
  D. Corps of Engineers Appendix C
  E. Emergencies and Historic Preservation
  F. Transportation Issues
  G. Section 106 Cases
VIII. Communications, Education, and Outreach Committee
  A. 2009 Preserve America Presidential Awards
  B. Department of Education/ACHP Initiatives
IX. Chairman's Report
  A. ACHP Alumni Foundation
  B. ACHP FY 2009 Appropriation/FY 2010 Budget Estimates
X. Executive Director's Report
  A. Old Post Office Redevelopment Legislation
  B. OFAP Director Recruitment
XI. New Business
XII. Adjourn

Note: The meetings of the ACHP are open to the public.

If you need special accommodations due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Room 803, Washington, DC, 202–606–8503, at least seven (7) days prior to the meeting. For further information: Additional information concerning the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., #803, Washington, DC 20004.

Dated: November 4, 2008.

John Fowler,
Executive Director.

[FR Doc. E8–26652 Filed 11–10–08; 8:45 am]

BILLING CODE 4310–K6–M

AGENCY FOR INTERNATIONAL DEVELOPMENT

Senior Executive Service: Membership of Performance Review Board

ACTION: Notice.

SUMMARY: This notice lists approved candidates who will comprise a standing roster for service on the Agency's SES Performance Review Board. The Agency will use this roster to select SES board members, and an outside member for the convening SES Performance Review Board each year. The standing roster is as follows:

Mauricio Vera, Chairperson;
Angelique Crumbly, Alternate;
Franklin Moore;
Susan Pascocello;
James Peters, Alternate;
Randy Streufert;
Karen Higgenbotham, Outside Member.

FOR FURTHER INFORMATION CONTACT: Melissa Jackson, 202–712–1781.

Dated: November 3, 2008.

Agnes D'Alessandro,
Chief, Employee and Labor Relations and Benefits Division.

[FR Doc. E8–26800 Filed 11–10–08; 8:45 am]

BILLING CODE 6116–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 5, 2008.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: National Animal Identification System.

OMB Control Number: 0579–0259.

Summary of Collection: The Animal and Plant Health Inspection Service (APHIS) regulates the importation and interstate movement of animals and animal products and conducts various other activities to protect the health of our Nation's livestock and poultry. The advent of increased animal disease outbreaks around the globe over the past decade, especially the recent BSE-positive cow found in Washington State, has intensified the public interest in developing a national animal identification program for the purpose of protecting animal health. Fundamental to controlling any disease threat, foreign or domestic, to the Nation's animal resources is to have a system that can identify individual animals or groups, the premises where they are located, and the date of entry to each premises. A national animal identification system is being implemented by APHIS at present on a voluntary basis. It is intended to identify all livestock, as well as record their movements over the course of their lifespan.

Need and Use of the Information: APHIS goal is to create an effective, uniform, consistent, and efficient system that when fully implemented, will allow traces to be completed within 48 hours of detection of a disease, ensuring rapid containment of the disease. Successful implementation of the animal identification and tracking systems will depend on the effective use of three primary information collection activities: Premises and nonproducer participants identification records, individual animal identification transaction records, and group/lot transaction records that will be created and maintained through various industry and Government collaborative efforts. Failing to collect the needed information would make it impossible to conduct a timely traceback of animals potentially exposed to a disease of concern.

Description of Respondents: Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 500,472.

Frequency of Responses: Recordkeeping;

Reporting: On occasion.

Total Burden Hours: 2,832,437.

Animal and Plant Health Inspection Service

Title: Importation of Fruits and Vegetables.

OMB Control Number: 0579–0264.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests. Regulations contained in Title 7 of the Code of Federal Regulations, Part 319 (Subpart—Fruit and Vegetables), Sections 319.56 *et seq.,* implement the intent of the this Act by prohibiting or restricting the importation of certain fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of fruit flies and other injurious plant pests that are new to the United States or not widely distributed within the United States. These regulations are enforced by the Plant Protection and quarantine, a program with USDA's Animal and Plant Health Inspection Service (APHIS).

Need and Use of the Information: The use of certain information collection activities including phytosanitary certificates, fruit fly monitoring records, and cooperative agreements will be used to allow the entry of certain fruits and vegetables into the United States. Without the information all shipments would need to be inspected very thoroughly, thereby requiring considerably more time and would slow the clearance of international shipments.

Description of Respondents: Business or other for-profit; Federal Government.

Number of Respondents: 15.

Frequency of Responses: Recordkeeping;

Reporting: On occasion.

Total Burden Hours: 123.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. E8–26743 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Request for Extension of a Currently Approved Information Collection; End-Use Certificate Program

AGENCY: Farm Service Agency, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is seeking comments from all interested individuals and organizations on an extension of a currently approved information collection that supports the End-Use Certificate Program.

DATES: Comments on this notice must be received on or before January 12, 2009 to be assured consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

Mail: Sharon Miner, USDA, Farm Service Agency, Commodity Operations Division, 1400 Independence Avenue, SW., STOP 0553, Washington, DC 20250–0553.

E-mail: Send comment to: *Sharon.Miner@wdc.usda.gov.*

Fax: (202) 690–3123.

Comments also should be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Sharon Miner, Commodity Operations Division, telephone (202) 720–6266.

SUPPLEMENTARY INFORMATION:

Title: End-Use Certificate Program.

OMB Control Number: 0560–0151.

Expiration Date of Approval: June 30, 2009.

Type of Request: Extension.

Abstract: This information collection is to ensure that Canadian wheat imported into the U.S. does not benefit from United States export programs. To comply with the provisions of the North American Free Trade Agreement Implementation Act, FSA requires information from the importers, subsequent buyers, and end-users that assist in tracking the Canadian wheat within the U.S. marketing system.

Estimate of Burden: Public reporting burden for this information collection is estimated to average 0.1744 hours per response.

Respondents: Wheat importers, traders, and end-users.

Estimated Number of Respondents: 421.

Estimated Number of Responses per Respondent: 128.

Estimated Total Annual Burden on Respondents: 4,520 hours.

Comments are invited on:

(1) Whether the continued collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the FSA's estimate of burden including validity of the methodology and assumptions used;

(3) Enhancing the quality, utility, and clarity of the information collected; or

(4) Minimizing the burden of the collection of the information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will become a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Signed in Washington, DC on November 5, 2008.

Thomas B. Hofeller,

Acting Administrator, Farm Service Agency.

[FR Doc. E8–26853 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Forest Service

Genesis, Inc. Exploration Drilling Project Kootenai National Forest, Lincoln County, MT

AGENCY: Forest Service, USDA.

ACTION: Revised Notice of intent to prepare an environmental impact statement.

SUMMARY: Genesis, Inc. submitted a revised Plan of Operations for exploration drilling near Troy, Montana. This revised plan adds drilling at seven sites on National Forest System Roads to the exploratory helicopter-assisted drilling described in the July 25, 2008, Notice of Intent to Prepare an Environmental Impact Statement (EIS).

Scoping Comment Date: Comments concerning the revised proposed action must be postmarked by December 8, 2008, to be considered in the draft EIS.

ADDRESSES: Send written comments concerning the Proposed Action to Mike Herrin, Three Rivers District Ranger, Genesis Exploration Project, Kootenai National Forest, 12858 U.S. Hwy 2, Troy, MT 59935, or e-mail your comments to: *comments-northern-kootenai-three-rivers@fs.fed.us.* All comments received must contain: Name of commenter, postal service mailing address, and date of comment. Comments sent as an e-mail message should be sent as an attachment to the message. A copy on computer-generated disc should accompany all comments over one page in length.

FOR FURTHER INFORMATION CONTACT: Dick Harlow, Project Coordinator, Three River Ranger Station, 12858 U.S. Hwy 2, Troy, Montana 59935. Phone (406) 293–7773, or e-mail at *dharlow@fs.fed.us.*

SUPPLEMENTARY INFORMATION:

Proposed Action

The Three Rivers District Ranger of the Kootenai National Forest has received a revised plan of operations proposing exploration drilling in two phases.

Phase 1 adds previously authorized (Mount Vernon Exploratory Drilling Decision Memo, February 2004), but uncompleted, exploratory drilling activities located in Section 6, T28N, R33W, P.M.M., Lincoln County, Montana. This phase consists of 12 core holes from seven drill sites on National Forest System Roads 4628 and 4628A with no additional surface disturbance. The sites are approximately 100 feet long by 20 feet wide, and the holes are estimated to average 1,200 feet in depth. A diamond drill mounted on a trailer or skid would be utilized and pulled into position with a pickup or tractor. The drill schedule would be two shifts per day, seven days per week. The new timeframe for this phase is two years.

Phase 2 includes access to three (3) helicopter supported drill sites on NFS lands in sections 7, 17, 18, T28N, R33W, MT. P.M., southwest of Bull Lake, in Lincoln and Sanders Counties. These sites are within the Scotchman Peaks #662 Inventoried Roadless Area. All three sites were previously drilled in 1999, and this additional exploration drilling is needed to further define ore reserves on the unpatented mining claims. The proposal is to drill 8 core holes from three separate locations, utilizing existing openings from previous helicopter drill sites. The holes will vary from 100′ to 1600′ in depth. The Drilling Plan for the drill sites is to use a preconstructed metal landing/drill platform (approx. 30′ long × 15′ wide). The platform will be flown to the sites in sections and assembled. The drill will be mounted on the drill platforms on the south side of Ross Creek. A helicopter staging site will be located near the junction of FR 4628 and FR 4628A. Some site maintenance will be required. This work will include removal of brush and short trees.

Design features and mitigations to maintain and protect resource values would be included.

The proposed implementation period would begin in the fall of 2009 and reclamation would be completed by December 15, 2012.

Lead and Cooperating Agencies

Montana Department of Environmental Quality, U.S. Fish and Wildlife Service, Montana Department of Natural Resources and Conservation, Confederated Salish and Kootenai Tribes, and Kootenai Tribe of Idaho, have either jurisdiction or interest and will participate as cooperating agencies or government entities in the preparation of this EIS. Other governmental agencies and any public that may be interested in or affected by the proposal are invited to participate in the scoping process, which is designed to obtain input and to identify potential issues relating to the proposed project.

Responsible Official

As the District Ranger of the Three Rivers Ranger District, Kootenai National Forest, I am the Responsible Official. As the Responsible Official, I will decide if the proposed project will be implemented. I will document the decision and reasons for the decision in the Record of Decision.

Range of Alternatives

The Forest Service will consider a range of alternatives. One of these will be the ''no action'' alternative in which none of the proposed activities will be implemented. Additional alternatives will examine varying levels and locations for the proposed activities to

achieve the proposal's purposes, as well as to respond to the issues and other resource values.

Nature of Decision To Be Made

The nature of the decision to be made is to select an action that meets the legal rights of the proponent, while protecting the environment in compliance with applicable laws, regulations and policy. The District Ranger will use the EIS process to develop the necessary information to make an informed decision as required by 36 CFR 228 Subpart A. Based on the alternatives developed in the EIS, the following are possible decisions:

1) An approval of the Plan of Operations as submitted;

2) An approval of the Plan of Operations with changes, and the incorporation of mitigations and stipulations that meet the mandates of applicable laws, regulations, and policy;

3) Denial of the Plan of Operations if no alternative can be developed that is in compliance with applicable laws, regulations and policy.

Permits or Licenses Required

Various permits and licenses are needed prior to implementation of this project. Permits or licenses required by the issuing agencies identified for this proposal are:

- Approval of Plan of Operations from the Kootenai National Forest.
- Exploration License from the Montana Department of Environmental Quality.

Public Involvement and Scoping: This Revised Notice of Intent offers an additional scoping period to that given in the original Notice. Comments submitted previously do not need to be resubmitted. Comments concerning the proposed action must be postmarked by December 8, 2008, to be considered in the draft EIS. The public is encouraged to take part in the process and to visit with Forest Service officials at any time during the analysis and prior to the decision. The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies, Tribal governments, and other individuals or organizations that may be interested in, or affected by, the proposed action. This input will be used in preparation of the draft and final EIS. The scoping process will include:

1. Identifying potential issues.
2. Identifying major issues to be analyzed in depth.
3. Identifying alternatives to the proposed action.
4. Exploring additional alternatives that will be derived from issues recognized during scoping activities.
5. Identifying potential environmental effects of this proposal (i.e., direct, indirect, and cumulative effects and connected actions).

Revised Estimated Dates for Filing: The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review in February 2008. At that time EPA will publish a Notice of Availability of the draft EIS in the **Federal Register**. The comment period on the draft EIS will be 45 days from the date the EPA publishes the Notice of Availability in the **Federal Register**. It is very important that those interested in the management of this area participate at that time.

The final EIS is scheduled to be completed in May 2009. In the final EIS, the Forest Service is required to respond to comments and responses received during the comment period that pertain to the environmental consequences discussed in the draft EIS and to applicable laws, regulations, and policies considered in making a decision regarding the proposal.

Reviewer's Obligations: The Forest Service believes it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider and respond to them in the final EIS.

To be most helpful, comments on the draft EIS should be as specific as possible and may address the adequacy of the statement or the merit of the alternatives discussed. Reviewers may wish to refer to the Council on Environmental Quality regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal, and will **be** available for public inspection.

Authority: 40 CF 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21).

Dated: October 29, 2008.

Mike Herrin,

District Ranger, Three Rivers Ranger District, Kootenai National Forest.

[FR Doc. E8–26677 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 63–2008]

Foreign–Trade Zone 120 Cowlitz County, Washington, Application for SubzoneShin–Etsu Handotai America, Inc. (Semiconductor–Grade Silicon Wafers), Vancouver, Washington

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the Cowlitz County Economic Development Council, grantee of FTZ 120, requesting special–purpose subzone status for the semiconductor–grade silicon wafer manufacturing facility of Shin–Etsu Handotai America, Inc. (SEH–A), located in Vancouver, Washington. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on October 30, 2008.

The SEH–A facility (882 employees, 135 acres, 1.6 million square feet) is located at 4111 NE 112th Avenue, Vancouver, Washington. The facility is used for the manufacturing of semiconductor–grade silicon ingots and wafers. Components and materials sourced from abroad (representing 5–15% of the value of the finished product) include: processed carbides of silicon, propylene glycol, acyclic polyamine, organic surface active agents, glues and other adhesives, organic reaction initiators, alumina silicate compounds, eslon solvent cements, anti–scruff paste, rust inhibitors, press coolants, polyamides, silicones, and plastic boxes and bags (duty rate ranges from duty–free to 6.5%).

FTZ procedures could exempt SEH–A from customs duty payments on the foreign components used in export production. The company anticipates that between 60 and 70 percent of the

plant's shipments will be exported. On its domestic sales, SEH–A would be able to choose the duty rates during customs entry procedures that apply to finished semiconductor–grade silicon ingots and wafers (duty–free) for the foreign inputs noted above. SEH–A also plans to realize logistical benefits through the use of weekly customs entry procedures. Customs duties also could possibly be deferred or reduced on foreign status production equipment. The request indicates that the savings from FTZ procedures would help improve the plant's international competitiveness.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 12, 2009. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 26, 2009.

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:U.S. Department of Commerce Export Assistance Center, 2601 Fourth Ave., Suite 320, Seattle, Washington 98121.Office of the Executive Secretary, Foreign–Trade Zones Board, U.S. Department of Commerce, Room 2111, 1401 Constitution Ave. NW, Washington, DC 20230.

For further information, contact Elizabeth Whiteman at Elizabeth__Whiteman@ita.doc.gov or (202) 482–0473.

Dated: November 3, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–26838 Filed 11–10–08; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Notice of Initiation of Antidumping Duty Changed Circumstances Review: Carbon and Certain Alloy Steel Wire Rod From Mexico

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

ACTION: Notice of Initiation of Antidumping Duty Changed Circumstances Review: Carbon and Certain Alloy Steel Wire Rod From Mexico.

SUMMARY: In response to a request from Ternium Mexico, S.A. de C.V. (Ternium), a producer of steel wire rod, and Hylsa S.A. de C.V. (Hylsa), a service company that provides services to Ternium on a contract basis, and pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216 and 351.221(c)(3), the Department is initiating a changed circumstances review of the antidumping order on carbon and certain alloy steel wire rod from Mexico. This review will determine whether Ternium is the successor-in-interest to Hylsa.

DATES: *Effective Date:* November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Jolanta Lawska, Office of AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–8362.

Background

On October 29, 2002, the Department published in the **Federal Register** the antidumping duty order on wire rod from Mexico; *see Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod From Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine*, 67 FR 65945 (October 29, 2002) (*Wire Rod Order*). On September 3, 2008, Ternium filed a request for a changed circumstances review of the *Wire Rod Order*, claiming that Hylsa, the respondent in the original investigation, has changed its name to Ternium. Ternium has requested that the Department determine whether it is the successor-in-interest to Hylsa, in accordance with section 751(b) of the Act and 19 CFR 351.216. In addition, Ternium submitted documentation in support of its claim. In response to Ternium's request, the Department is initiating a changed circumstances review of this order.

Scope of the Order

The merchandise subject to this order is certain hot-rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above-noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (''HTSUS'') definitions for (a) stainless steel; (b) tool steel; (c) high nickel steel; (d) ball bearing steel; (e) concrete reinforcing bars and rods; and (f) free machining steel products (*i.e.*, products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod and 1080 grade tire bead quality wire rod. This grade 1080 tire cord quality rod is defined as: (i) Grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non-deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

This grade 1080 tire bead quality rod is defined as: (i) Grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non-deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1)

0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

For purposes of the grade 1080 tire cord quality wire rod and the grade 1080 tire bead quality wire rod, an inclusion will be considered to be deformable if its ratio of length (measured along the axis—that is, the direction of rolling—of the rod) over thickness (measured on the same inclusion in a direction perpendicular to the axis of the rod) is equal to or greater than three. The size of an inclusion for purposes of the 20 microns and 35 microns limitations is the measurement of the largest dimension observed on a longitudinal section measured in a direction perpendicular to the axis of the rod. This measurement methodology applies only to inclusions on certain grade 1080 tire cord quality wire rod and certain grade 1080 tire bead quality wire rod that are entered, or withdrawn from warehouse, for consumption on or after July 24, 2003.

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should the petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end-use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products subject to this order are currently classifiable under subheadings 7213.91.3011, 7213.91.3015, 7213.91.3092, 7213.91.4500, 7213.91.6000, 7213.99.0030, 7213.99.0090, 7227.20.0000, 7227.90.6010, and 7227.90.6080 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.[1]

Initiation of Antidumping Duty Changed Circumstances Review

Pursuant to section 751(b)(1) of the Act, the Department will conduct a changed circumstances review upon receipt of a request from an interested party or receipt of information concerning an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. On September 3, 2008, Ternium submitted its request for a changed circumstances review. With its request, Ternium submitted certain information related to its claim that Hylsa changed its name to Ternium, including information describing the acquisition of Hylsa by Ternium Luxembourg and changes in Hylsa's operating and corporate structure immediately following that acquisition. Based on the information Ternium submitted, the Department has determined that changed circumstances sufficient to warrant a review exist. *See* 19 CFR 351.216(d). In antidumping duty changed circumstances reviews involving a successor-in-interest determination, the Department typically examines several factors including, but not limited to: (1) Management; (2) production facilities; (3) supplier relationships, and (4) customer base. *See Brass Sheet and Strip From Canada: Final Results of Antidumping Duty Administrative Review*, 57 FR 20460, 20462 (May 13, 1992) and *Certain Cut-To-Length Carbon Steel Plate from Romania: Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review*, 70 FR 22847 (May 3, 2005) (*Plate from Romania*), unchanged in the *Notice of Final Results of Antidumping Duty Changed Circumstances Review: Certain Cut-to-Length Carbon Steel Plate From Romania*, 70 FR 35624 (June 21, 2005). While no single factor or combination of factors will necessarily be dispositive, the Department generally will consider the new company to be the successor to the predecessor company if the resulting operations are essentially the same as those of the predecessor company. *See, e.g., Industrial Phosphoric Acid From Israel: Final Results of Antidumping Duty Changed Circumstances Review*, 59 FR 6944, 6945 (February 14, 1994), and *Plate From Romania*, 70 FR 22847. Thus, if the record evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the predecessor company, the Department may assign the new company the cash deposit rate of its predecessor. *See, e.g., Fresh and Chilled Atlantic Salmon From Norway: Final Results of Changed Circumstances Antidumping Duty Administrative Review*, 64 FR 9979, 9980 (March 1, 1999). Although Ternium submitted documentation related to its name change and some limited information regarding the four factors that the Department considers in its successor-in-interest analysis, it did not provide complete supporting documentation for the four elements listed above. Accordingly, the Department has determined that it would be inappropriate to expedite this action by combining the preliminary results of review with this notice of initiation, as permitted on 19 CFR 351.221(c)(3)(ii). Therefore, the Department is not issuing the preliminary results of its antidumping duty changed circumstances review at this time.

The Department will issue questionnaires requesting additional information for the review and will publish in the **Federal Register** a notice of the preliminary results of the antidumping duty changed circumstances review, in accordance with 19 CFR 351.221(b)(2) and (4), and 19 CFR 351.221(c)(3)(i). This notice will set forth the factual and legal conclusions upon which our preliminary results are based and a description of any action proposed. Pursuant to 19 CFR 351.221(b)(4)(ii), interested parties will have an opportunity to comment on the preliminary results of review. In accordance with 19 CFR 351.216(e), the Department will issue the final results of its antidumping duty changed circumstances review not later than 270 days after the date on which the review is initiated.

During the course of this antidumping duty changed circumstances review, deposit requirements for the subject merchandise exported and manufactured by Ternium will continue to be the rate established in the final results of the last administrative review for all other manufacturers and exporters not previously reviewed. *See Carbon and Certain Alloy Steel Wire Rod From Mexico: Notice of Final*

[1] Effective January 1, 2006, U.S. Customs and Border Protection (CBP) reclassified certain HTSUS numbers related to the subject merchandise. *See http://hotdocs.usitc.gov/tariff_chapters_current/toc.html.*

Results of Antidumping Duty Administrative Review, 73 FR 13532 (March 13, 2008). The cash deposit will be altered, if warranted, pursuant only to the final results of this review.

This notice of initiation is in accordance with section 751(b)(1) of the Act, 19 CFR 351.216(b) and (d), and 19 CFR 351.221(b)(1).

Dated: November 6, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–26954 Filed 11–7–08; 4:15 pm]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–816]

Corrosion–Resistant Carbon Steel Flat Products From the Republic of Korea: Extension of Time Limits for the Final Results of Antidumping Duty Administrative Review

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

FOR FURTHER INFORMATION CONTACT: Cindy Robinson at (202) 482–3797, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On September 25, 2007, the U.S. Department of Commerce (''Department'') published a notice of initiation of the administrative review of the antidumping duty order on corrosion–resistant carbon steel flat products from Korea, covering the period August 1, 2006, to July 31, 2007. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 72 FR 54428 (September 25, 2007). On September 9, 2008, the Department published the preliminary results of this review. *See Certain Corrosion–Resistant Carbon Steel Flat Products From the Republic of Korea: Notice of Preliminary Results of the Antidumping Duty Administrative Review*, 73 FR 52267 (September 9, 2008). The final results of this review are currently due no later than January 7, 2009.

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (AAct@), requires the Department to issue the final results of a review within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within that time period, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the final results to a maximum of 180 days. *See also* 19 CFR 351.213(h)(2).

We determine that it is not practicable to complete the final results of this review within the original time limit because several technical issues have arisen. These issues include: (1) Whether to add a separate field to differentiate laminated products from painted products based on the physical, cost, and price differences of the two, and therefore to modify the Department's model–match methodology; (2) whether to recalculate the general and administrative and financial ratios; and (3) whether to exclude gains and losses on currency forward contracts. These issues require additional analyses of certain information. Therefore, the Department is fully extending the final results. The final results are now due not later than March 8, 2009. As this day falls on a Sunday, the final results are due March 9, 2009. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant of the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

This extension is in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: November 4, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–26837 Filed 11–10–08; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–811]

Purified Carboxymethylcellulose From the Netherlands: Partial Rescission of Antidumping Duty Administrative Review

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

SUMMARY: In response to requests from respondent Akzo Nobel Functional Chemicals, B.V. (''Akzo Nobel'') and Aqualon Company (''Petitioner''), the Department of Commerce (''Department'') initiated an administrative review of the antidumping duty order on purified carboxymethylcellulose (''CMC'') from the Netherlands. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 73 FR 50308 (August 26, 2008) (''*Initiation Notice*''). This administrative review covers the period July 1, 2007, through June 30, 2008. Due to the withdrawal of the requests for the administrative review by both parties, we are rescinding this review with respect to Akzo Nobel.

EFFECTIVE DATE: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen Bailey or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0193 or (202) 482–3019, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published an antidumping duty order on purified CMC from the Netherlands on July 11, 2005. *See Notice of Antidumping Duty Orders: Purified Carboxymethylcellulose from Finland, Mexico, the Netherlands and Sweden*, 70 FR 39734 (July 11, 2005). The Department published a notice of ''Opportunity to Request an Administrative Review'' of the antidumping duty order for the period July 1, 2007, through June 30, 2008, on July 11, 2008. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 73 FR 39948 (July 11, 2008). On July 14, 2008, Petitioner timely requested that the Department conduct an administrative review of sales of merchandise by Akzo Nobel and CP Kelco B.V. covered by the order. On July 31, 2008, Akzo Nobel timely requested that the Department conduct an administrative review of its sales of merchandise covered by the order. In response to both requests, the Department initiated the antidumping duty administrative review on purified CMC from the Netherlands on August 26, 2008. *See Initiation Notice*.

Akzo Nobel timely withdrew its request for review on October 9, 2008. Petitioner timely withdrew its request for review of sales by Akzo Nobel on October 10, 2008. *See* 19 CFR 351.213(d)(1).

Partial Rescission of the Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative

review, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. The Secretary may extend this time limit if the Secretary decides that it is reasonable to do so. *See* 19 CFR 351.213(d)(1). Both Petitioner and Akzo Nobel withdrew their requests for review with respect to the latter within the 90-day time limit. Therefore, in response to the withdrawal of requests for administrative reviews by both Akzo Nobel and Petitioner, the Department hereby rescinds the administrative review of the antidumping duty order on purified CMC from the Netherlands for the period July 1, 2007, through June 30, 2008 for Akzo Nobel.

Assessment Rates

The Department intends to issue assessment instructions to the U.S. Customs and Border Protection (''CBP'') 15 days after the date of publication of this partial rescission of administrative review. The Department will direct CBP to assess antidumping duties for Akzo Nobel at the cash deposit rate in effect on the date of entry for entries during the period July 1, 2007, through June 30, 2008.

Notification to Importers

This notice serves as a final reminder to importers for whom this review is being rescinded, of their responsibility under 19 CFR 351.402(f) to file a certificate regarding reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: November 4, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–26836 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. [0810011295–81297–01]]

Announcing DRAFT Federal Information Processing Standard (FIPS) Publication 186–3, Digital Signature Standard (DSS) and Request for Comments

AGENCY: National Institute of Standards and Technology (NIST), Commerce Department.

ACTION: Notice.

SUMMARY: This notice announces a second public review and comment period for Draft Federal Information Processing Standard 186–3, Digital Signature Standard. The draft standard, designated ''Draft FIPS 186–3,'' is proposed to revise and supersede FIPS 186–2. Draft FIPS 186–3 is a revision of FIPS 186–2, the Digital Signature Standard. The Draft FIPS specifies three techniques for the generation and verification of digital signatures that can be used for the protection of data: the Digital Signature Algorithm (DSA), the Elliptic Curve Digital Signature Algorithm (ECDSA) and the Rivest-Shamir-Adelman (RSA) algorithm. Although all three of these algorithms were approved in FIPS 186–2, this revision increases the key sizes allowed for DSA, provides additional requirements for the use of RSA and ECDSA, and includes requirements for obtaining the assurances necessary for valid digital signatures. FIPS 186–2 contained specifications for random number generators (RNGs); this revision does not include such specifications, but refers to NIST Special Publication (SP) 800–90 for obtaining random numbers.

Prior to the submission of this proposed standard to the Secretary of Commerce for review and approval, it is essential that consideration is given to the needs and views of the public, users, the information technology industry, and Federal, State and local government organizations. The purpose of this notice is to solicit such views.

DATES: Comments must be received on or before December 12, 2008.

ADDRESSES: Written comments may be sent to: Chief, Computer Security Division, Information Technology Laboratory, Attention: Comments on Draft FIPS 186–3, 100 Bureau Drive—Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930. Electronic comments may also be sent to: *ebarker@nist.gov.*

FOR FURTHER INFORMATION CONTACT: Elaine Barker, (301) 975–2911, National Institute of Standards and Technology, 100 Bureau Drive, STOP 8930, Gaithersburg, MD 20899–8930, *e-mail: elaine.barker@nist.gov.*

SUPPLEMENTARY INFORMATION: FIPS 186, first published in 1994, specified a digital signature algorithm (DSA) to generate and verify digital signatures. Later revisions (FIPS 186–1 and FIPS 186–2, adopted in 1998 and 1999, respectively) adopted two additional algorithms specified in American National Standards (ANS) X9.31 (Digital Signatures Using Reversible Public Key Cryptography for the Financial Services Industry (rDSA)), and X9.62 (The Elliptic Curve Digital Signature Algorithm (ECDSA)).

The original DSA algorithm, as specified in FIPS 186, 186–1 and 186–2, allows key sizes of 512 to 1024 bits. With advances in technology, it is prudent to consider larger key sizes. Draft FIPS 186–3 allows the use of 1024, 2048 and 3072-bit keys. Other requirements have also been added concerning the use of ANS X9.31 and ANS X9.62. In addition, the use of the RSA algorithm as specified in Public Key Cryptography Standard (PKCS) #1 (RSA Cryptography Standard) is allowed.

A request for public comments was published in the **Federal Register** on March 13, 2006 (71 FR 12678). After receiving comments in response to this notice, NIST incorporated the comments and posted a revised version of the FIPS on its Web site. NIST received some additional comments in response to this posting. In all, a total of 15 individuals and organizations provided comments (two U.S. government agencies, a foreign government agency, one university, eight private organizations, and three from individuals). The following is a summary of the comments received and NIST's responses to them:

Comment: Seven commenters suggested a number of editorial changes.

Response: NIST made the appropriate editorial changes, which included correcting typographical errors; spelling, format and font size changes; reference restrictions and updates, where appropriate; minor word changes and clarifications.

Comment: One commenter requested that examples be provided for each of the digital signatures algorithms and key sizes.

Response: Examples will be provided at *http://csrc.nist.gov/groups/ST/toolkit/examples.html*, and a link to this Web page has been included in the implementation section of the announcement.

Comment: Eight commenters suggested a number of minor technical changes.

Response: The appropriate changes were made, which included:

Corrections to the input to and pseudocode for defined functions;

Corrections to table entries;

Removal of the appendix on timestamping, and placing the contents in a different document;

Allowing the use of the Chinese Remainder Theorem (CRT) for the representation of the private key; and

Stating that the minimum lengths for the auxiliary primes for the generation of RSA keys may be either fixed or randomly chosen.

Comment: Two commenters noted that the allowed values for the public exponent e differ significantly from those allowed in ANS X9.31 and PKCS #1.

Response: The restricted values in the FIPS are a Federal government choice to provide a higher level of security for its agencies. Non-Federal government entities may voluntarily adopt these restrictions.

Comment: One commenter asked why the new DSA domain parameter validation method in A.1.1.3 is not compatible with the old verification method in A.1.1.1, since the change breaks interoperability with the FIPS 186–2 generation method.

Response: A.1.1.3 is intentionally different from A.1.1.1. The change in the use of the hash function (no XORing) was in response to a cryptanalytic attack that showed how to select a set of domain parameters generated in the A.1.1.1 fashion in such a way that two ''messages'' with the same DSA signature could be found. Note that A.1.1.1 still allows domain parameters generated using the older method to be verified.

Comment: One commenter asked why the DSA key sizes are limited to the smaller values?

Response: The length of the larger keys has a huge impact on communications and storage requirements. The strategy of the U.S. government is to transition to elliptic curve algorithms in order to reduce the key sizes.

Comment: One commenter asked that a specification of the Shawe-Taylor algorithm be included for use in the generation of RSA primes, as well as for DSA primes.

Response: The Shawe-Taylor method was rewritten as a general routine that is used for both DSA and RSA prime generation.

Comment: Two commenters provided comments with regard to the inconsistencies in the number of iterations required for the probabilistic primality tests.

Response: The number of iterations was taken from several FIPS and ANSI standards. As a result of these comments, NIST reviewed the methods used to calculate the number of iterations and calculated new values for each digital signature method and prime length.

After the proposed values and associated explanatory text were posted on the NIST Web site (in January 2007) the following five comments were received:

Comment: One commenter stated the values in ANS X9.80 (Prime Number Generation, Primality Testing, and Primality Certificates) should be used for the number of iterations.

Response: The values ANS X9.80 were based on assumptions and estimates that have been superseded by more recent considerations, and these newer values have been included the FIPS.

Comment: One commenter suggested that fewer categories be provided in the tables.

Response: NIST has chosen to base the number of tests on the key sizes and provided separate requirements for each. An implementer can choose to combine the requirements into fewer categories, as long as the number of rounds for each key size are equal to or greater than the numbers provided in the FIPS.

Comment: One commenter felt that the error probability should always be 2^{-100} to align with the ANSI standards.

Response: The 2^{-100} error probability is included in FIPS 186–3, along with others that are dependent on the security strength, to allow an implementer to select the most suitable probability for their application.

Comment: One commenter asked why the Lucas test is not required in some cases?

Response: After extensive analysis by NIST, it was determined the Lucas test is not required. However, the test can be performed after the required number of iterations of the Miller-Rabin tests in order to provide higher assurance. Wording has been included to clarify this.

Comment: One commenter suggested that the Frobenius-Grantham (FG) method for prime candidate testing should be included, in addition to the Miller-Rabin (MR) and Lucas tests.

Response: NIST has decided to remain with the testing methods used in ANS X9.31, which includes the MR and Lucas tests, but not the FG tests. In addition, the FG tests are more complex, so would be more likely to be implemented incorrectly.

Comment: The criteria for the generation of strong primes in ASC X9.31, upon which RSA key generation is based, does not agree with the definition of strong primes in the Handbook of Applied Cryptography (HAC).

Response: NIST researched and analyzed the requirements for RSA key pair generation, including requirements for the use of strong primes, and determined that strong primes as defined by the HAC are not required. The RSA key pair generation methods were modified to include a number of different methods that were not previously included in the draft FIPS.

Comment: The draft FIPS refers to approved random number generators. It is not clear whether SP 800–90 contains the only approved methods for random number generation, or if other approved methods can be used.

Response: The only other NIST document containing approved methods for random number generation is FIPS 186–2. With the approval of FIPS 186–3, those methods will no longer be approved, subject to a transition period posted by the Cryptographic Module Validation Program (CMVP).

NIST has incorporated the comments previously received as described above. NIST now seeks public comments on the revised draft of FIPS 186–3. This second draft of FIPS 186–3 is available electronically from the NIST Web site at: *http://csrc.nist.gov/publications/drafts.html.* The current FIPS 186–2 is available electronically from the NIST Web site at: *http://csrc.nist.gov/publications/fips/index.html.* The first draft of FIPS 186–3 and comments received on that draft are available electronically from the NIST Web site at: *http://csrc.nist.gov/groups/ST/toolkit/digital_signatures.html*, respectively. Comments received in response to this notice will be published electronically at *http://csrc.nist.gov/groups/ST/toolkit/digital_signatures.html.*

Authority: In accordance the Federal Information Security Management Act (FISMA) of 2002 (Pub. L. 107–347), the

Secretary of Commerce is authorized to approve Federal Information Processing Standards (FIPS). NIST activities to develop computer security standards to protect Federal sensitive (unclassified) information systems are undertaken pursuant to specific responsibilities assigned to NIST by section 20 of the National Institute of Standards and Technology Act (5 U.S.C. 278g–3), as amended by section 303 of the Federal Information Security Management Act of 2002.

Executive Order 12866: This notice has been determined not to be significant for the purposes of Executive Order 12866.

Dated: November 5, 2008.

Patrick Gallagher,

Deputy Director.

[FR Doc. E8–26841 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcing a Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology.

ACTION: Meeting notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., notice is hereby given that the Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, December 3, 2008 from 8:30 p.m. until 5 p.m., Thursday, December 4, 2008, from 8:30 a.m. until 5 p.m., and Friday, December 5, 2008 from 8 a.m. until 5:15 p.m. All sessions will be open to the public. The Advisory Board was established by the Computer Security Act of 1987 (Pub. L. 100–235) and amended by the Federal Information Security Management Act of 2002 (Pub. L. 107–347) to advise the Secretary of Commerce and the Director of NIST on security and privacy issues pertaining to federal computer systems. Details regarding the Board's activities are available at *http://csrc.nist.gov/groups/SMA/ispab/index.html/.*

DATES: The meeting will be held on December 3, 2008 from 8:30 p.m. until 5 p.m., December 4, 2008 from 8:30 a.m. until 5 p.m. and December 5, 2008, from 8 a.m. until 5:15 p.m.

ADDRESSES: The meeting will take place at George Washington University Cafritz Conference Center 800 21st Street, NW., Washington, DC, Room 405, on December 3 and 4, 2008 and 3rd Floor Continental Ballroom on December 5, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Pauline Bowen, Board Secretariat, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, *telephone:* (301) 975–2938.

SUPPLEMENTARY INFORMATION:

Agenda:

—Welcome and Overview
—OMB Update
—USCERT and Einstein
—ID Management
—Privacy Technology Report
—Center for Strategic and International Studies (CSIS) Commission Briefing
—ISC2 Software Credentialing
—Metrics and FISMA 08
—ISPAB Work Plan Discussion
—SCADA Security
—Threat Analysis, IC to Civilian
—Panel—Cloud Computing—Basics
—Panel—Cloud Computing—Security Strengths and Challenges
—Panel—Virtualization—Basics
—Panel—Cloud Computing and Virtualization

Note that agenda items may change without notice because of possible unexpected schedule conflicts of presenters. The final agenda will be posted on the Web site indicated above.

Public Participation: The Board agenda will include a period of time, not to exceed thirty minutes, for oral comments and questions from the public (Thursday, December 5, 2008 at 3:45–4:15 p.m.). Each speaker will be limited to five minutes. Members of the public who are interested in speaking are asked to contact the Board Secretariat at the telephone number indicated above. In addition, written statements are invited and may be submitted to the Board at any time. Written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930. Approximately 15 seats will be available for the public and media on December 3 and 4, 2008 and approximately 200 seats will be available for the public and media on December 5, 2008.

Dated: November 5, 2008.

Patrick Gallagher,

Deputy Director.

[FR Doc. E8–26840 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–AV00

Atlantic Highly Migratory Species; Essential Fish Habitat

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

ACTION: Extension of comment period.

SUMMARY: In order to provide additional opportunities for the public, the Atlantic Regional Fishery Management Councils, the Atlantic and Gulf States Marine Fisheries Commissions, and other interested parties to comment on the Essential Fish Habitat Draft Amendment 1 to the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), NMFS is extending the comment period for this action. On September 19, 2008, NMFS published a Notice of Availability (NOA) of a draft environmental impact statement and a fishery management plan amendment. Based on the September 19, 2008, notice, the comment period was scheduled to conclude on November 18, 2008. NMFS is now extending the comment period until December 12, 2008. Comments received by NMFS on the Draft Amendment will be used in the development of Final Amendment 1 to the 2006 Consolidated HMS FMP.

DATES: The deadline for comments on Draft Amendment 1 has been extended from November 18, 2008, as published on September 19, 2008 (73 FR 54384), to 5:00 p.m. on December 12, 2008.

ADDRESSES: Written comments on this action should be sent to Chris Rilling, Highly Migratory Species Management Division by any of the following methods:

- E–mail: *HMSEFH@noaa.gov.*
- Mail: 1315 East–West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope ''Comments on EFH Amendment to HMS FMP.''
- Fax: 301–713–1917.

Copies of Draft Amendment 1 to the Consolidated HMS FMP are available from the HMS website under ''Breaking News'' at *http://www.nmfs.noaa.gov/sfa/hms/* or by contacting Chris Rilling (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Chris Rilling or Sari Kiraly by phone at (301) 713–2347 or by fax at (301) 713–1917.

SUPPLEMENTARY INFORMATION: The Magnuson–Stevens Act (16 U.S.C. 1801

et seq.) requires the identification and description of EFH in FMPs and the consideration of actions to ensure the conservation and enhancement of such habitat. The EFH regulatory guidelines (50 CFR 600.815) state that NMFS should periodically review and revise EFH, as warranted, based on available information.

Draft Amendment 1 considers alternatives for revising EFH, designating a new Habitat Area of Particular Concern (HAPC) for bluefin tuna spawning areas in the Gulf of Mexico, and analyzes fishing impacts on EFH.

Due to the timing of the South Atlantic Fishery Management Council's meeting at the beginning of December, NMFS is extending the comment period to provide additional opportunity for the South Atlantic Fishery Management Council, and other interested parties to comment on Draft Amendment 1. Copies of Draft Amendment 1 to the Consolidated HMS FMP are available for review (see **ADDRESSES**). NMFS anticipates completing this document and any related documents by the summer of 2009.

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

Dated: November 4, 2008.

Emily H. Menashes

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

[FR Doc. E8–26852 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Commerce Spectrum Management Advisory Committee Meeting

AGENCY: National Telecommunications and Information Administration (NTIA), Department of Commerce (DOC)

ACTION: Notice of Open Meeting

SUMMARY: This notice announces a public meeting of the Spectrum Management Advisory Committee (Committee). The Committee provides advice to the Assistant Secretary for Communications and Information on spectrum management matters.

DATES: The meeting will be held on December 4, 2008, from 9:30 a.m. to 12:30 p.m., Eastern Standard Time.

ADDRESSES: The meeting will be held at the United States Department of Commerce, 1401 Constitution Ave. N.W., Room 5855 (the Secretary's Conference Room), Washington, DC 20230. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue N.W., Room 4725, Washington, DC 20230 or emailed to spectrumadvisory@ntia.doc.gov.

FOR FURTHER INFORMATION CONTACT: Eric Stark, Designated Federal Officer, at (202) 482–1880 or estark@ntia.doc.gov; Joe Gattuso at (202) 482–0977 or jgattuso@ntia.doc.gov; and/or visit NTIA's web site at www.ntia.doc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the Committee to implement a recommendation of the President's Initiative on Spectrum Management pursuant to the President's November 29, 2004 Memorandum for the Heads of Executive Departments andAgencies on the subject of ''Spectrum Management for the 21st Century.''[1] This Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and is consistent with the National Telecommunications and Information Administration Act, 47 U.S.C. § 904(b). The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information on needed reforms to domestic spectrum policies and management to enable the introduction of new spectrum-dependent technologies and services, including long-range spectrum planning and policy reforms for expediting the American public's access to broadband services, public safety, and digital television. The Committee functions solely as an advisory body in compliance with the FACA.

Matters to Be Considered: The Committee will consider a transition report and any remaining reports of its Technical Sharing Efficiencies and Operational Sharing Efficiencies subcommittees. It will provide an opportunity for public comment at the meeting.

Time and Date: The meeting will be held on December 4, 2008, from 9:30 a.m. to 12:30 p.m. Eastern Standard Time. The times and the agenda topics are subject to change. Please refer to NTIA's web site, http://www.ntia.doc.gov, for the most up-to-date meeting agenda.

Place: The meeting will be held at the United States Department of Commerce, 1401 Constitution Ave. N.W., Room 5855 (the Secretary's Conference Room), Washington, DC 20230. The meeting will be open to the public and press on a first-come, first-served basis. Space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring special services, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Gattuso, at (202) 482–0977 or jgattuso@ntia.doc.gov, at least five (5) business days before the meeting.

Status: Interested parties are invited to attend and to submit written comments with the Committee at any time before or after a meeting. Parties wishing to submit written comments for consideration by the Committee in advance of this meeting should send them to the above-listed address and must be received by close of business on December 1, 2008, to provide sufficient time for review. Comments received after December 1, 2008, will be distributed to the Committee but may not be reviewed prior to the meeting. It would be helpful if paper submissions also include a three and one-half inch computer diskette in HTML, ASCII, Word or WordPerfect format (please specify version). Diskettes should be labeled with the name and organizational affiliation of the filer, and the name of the word processing program used to create the document. Alternatively, comments may be submitted electronically to spectrumadvisory@ntia.doc.gov. Comments provided via electronic mail may also be submitted in one or more of the formats specified above.

Records: NTIA maintains records of all Committee proceedings. Committee records are available for public inspection at NTIA's office at the address above. Documents including the Committee's charter, membership list, agendas, minutes, and any reports are available on NTIA's Committee web page at http://www.ntia.doc.gov/advisory/spectrum.

Dated: November 6, 2008.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. E8–26871 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–60–S

[1] *President's Memorandum on Improving Spectrum Management for the 21st Century*, 49 Weekly Comp. Pres. Doc. 2875 (Nov. 29, 2004)(Executive Memorandum).

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Rules Relating to Regulation of Domestic Exchange-Traded Options

AGENCY: Commodity Futures Trading Commission.

ACTION: Extension of an Existing Collection.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on rules related to risk disclosure concerning exchange-traded commodity options.

DATES: Comments must be submitted on or before January 12, 2009.

ADDRESSES: Comments may be mailed to William Penner, Division of Clearing and Intermediary Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581.

FOR FURTHER INFORMATION CONTACT: William Penner, (202) 418–5407; *Fax:* (202) 418–5536; *e-mail: wpenner@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

Rules Relating to Regulation of Domestic Exchange-Traded Options, OMB Control Number 3038–0007—Extension

The rules require futures commission merchants and introducing brokers: (1) To provide their customers with standard risk disclosure statements concerning the risk of trading commodity interests; and (2) to retain all promotional material and the source of authority for information contained therein. The purpose of these rules is to ensure that customers are advised of the risks of trading commodity interests and to avoid fraud and misrepresentation. This information collection contains the recordkeeping and reporting requirements needed to ensure regulatory compliance with Commission rules relating to this issue.

The Commission estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Regulation	Estimated number of respondents or recordkeepers per year	Reports annually by each respondent	Total annual responses	Estimated average number of hours per response	Estimated total number of hours of annual burden in fiscal year
Reporting:					
38.3, 38.4, 40.2 and 40.3 (Procedure for designation or self-certification)	13.00	2.00	26.00	25.00	650.00
33.7—(Risk disclosure)	175.00	115.00	20,125.00	0.08	1,610.00
Subtotal (reporting requirements)	188.00	.....	20,151.00	.....	2,260.00
Recordkeeping:					
33.8—(Retention of promotional material)	225.00	1.00	225.00	25.00	5,625.00
Subtotal (recordkeeping requirements)	.....	.....	.....	.....	.....
Grand total (reporting and recordkeeping)	413.00	.....	20,376.00	.....	7,785.00

There are no capital costs or operating and maintenance costs associated with this collection.

Dated: November 5, 2008.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E8–26834 Filed 11–10–08; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Proposal To Exempt, Pursuant to the Authority in Section 4(c) of the Commodity Exchange Act, the Trading and Clearing of Certain Products Related to iShares® COMEX Gold Trust Shares and iShares® Silver Trust Shares

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed order and request for comment.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or the ''Commission'') is proposing to exempt the trading and clearing of certain contracts called ''options'' and other contracts called ''security futures'' on each of iShares® COMEX Gold Trust Shares (''Gold Products'') and iShares® Silver Trust Shares (''Silver Products'') (collectively, ''Gold and Silver Products''), proposed to be traded on national securities exchanges (as to options) and designated contract markets registered with the Securities and Exchange Commission (''SEC'') as limited purpose national securities associations (as to security futures), and in either case cleared through the Options Clearing Corporation (''OCC'') in its capacity as a registered securities clearing agency, from the provisions of the Commodity Exchange Act (''CEA'') [1] and the regulations thereunder, to the extent necessary to permit them to be so traded and cleared. Authority for this exemption is found in Section 4(c) of the CEA.[2]

DATES: Comments must be received on or before November 19, 2008.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: secretary@cftc.gov.* Include ''Options and Security Futures on Gold and Silver Products'' in the subject line of the message.
- *Fax:* 202–418–5521.
- *Mail:* Send to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *Courier:* Same as mail above.

All comments received will be posted without change to *http://www.CFTC.gov/.*

FOR FURTHER INFORMATION CONTACT: Robert B. Wasserman, Associate Director, 202–418–5092, *rwasserman@cftc.gov*, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

The OCC is both a Derivatives Clearing Organization (''DCO'') registered pursuant to Section 5b of the CEA,[3] and a securities clearing agency registered pursuant to Section 17A of the Securities Exchange Act of 1934 (''the '34 Act'').[4]

OCC has filed with the CFTC, pursuant to Section 5c(c) of the CEA and Commission Regulations 39.4(a) and 40.5 thereunder,[5] requests for approval of rules and rule amendments that would enable OCC (1) to clear and settle contracts called ''options'' (''Options'') on Gold and Silver Products traded on national securities exchanges, in its capacity as a registered securities clearing agency (and not in its capacity as a DCO) and (2) to clear and settle contracts called ''security futures'' (''Security Futures'') on Gold and Silver Products traded on designated contract markets [6] registered with the SEC as limited purpose national securities associations pursuant to Section 15A(k) of the '34 Act [7] (''DCMs'') as security futures subject to the CEA and CFTC regulations thereunder governing security futures, in either case in OCC's capacity as a registered securities clearing agency (and not in its capacity as a DCO).[8] Section 5c(c)(3) provides that the CFTC must approve such rules and rule amendments submitted for approval unless it finds that the rules or rule amendments would violate the CEA.

The request for approval concerning the Options and Security Futures on Gold and Silver Products was filed effective July 23, 2008. By letter dated August 20, 2008, the Director of the Division of Clearing and Intermediary Oversight, pursuant to delegated authority, extended the review period of the request until October 21, 2008 due to the novel and complex issues raised by the products that are the subject of the request. By letter dated October 16, 2008, OCC consented to an extension of the review period until November 20, 2008.

II. Section 4(c) of the Commodity Exchange Act

Section 4(c)(1) of the CEA empowers the CFTC to ''promote responsible economic or financial innovation and fair competition'' by exempting any transaction or class of transactions from any of the provisions of the CEA (subject to exceptions not relevant here) where the Commission determines that the exemption would be consistent with the public interest.[9] The Commission may grant such an exemption by rule, regulation or order, after notice and opportunity for hearing, and may do so on application of any person or on its own initiative.

In enacting Section 4(c), Congress noted that the goal of the provision ''is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.'' [10] Permitting Options and Security Futures on Gold and Silver Products to trade on national securities exchanges (as to Options) and DCMs (as to Security Futures) and in

[1] 7 U.S.C. 1 *et seq.*

[2] 7 U.S.C. 6(c).

[3] 7 U.S.C. 7a–1.

[4] 15 U.S.C. 78q–1.

[5] 7 U.S.C. 7a–2(c), 17 CFR 39.4(a), 40.5.

[6] *See* Section 5 of the CEA, 7 U.S.C. 7.

[7] 15 U.S.C. 78o–3(k).

[8] *See* SR–OCC–2008–13 and SR–OCC–2008–14. OCC has also filed these proposed rule changes with the Securities and Exchange Commission (''SEC'').

[9] Section 4(c)(1) of the CEA, 7 U.S.C. 6(c)(1), provides in full that: In order to promote responsible economic or financial innovation and fair competition, the Commission by rule, regulation, or order, after notice and opportunity for hearing, may (on its own initiative or on application of any person, including any board of trade designated or registered as a contract market or derivatives transaction execution facility for transactions for future delivery in any commodity under section 7 of this title) exempt any agreement, contract, or transaction (or class thereof) that is otherwise subject to subsection (a) of this section (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the agreement, contract, or transaction), either unconditionally or on stated terms or conditions or for stated periods and either retroactively or prospectively, or both, from any of the requirements of subsection (a) of this section, or from any other provision of this chapter (except subparagraphs (c)(ii) and (D) of section 2(a)(1) of this title, except that the Commission and the Securities and Exchange Commission may by rule, regulation, or order jointly exclude any agreement, contract, or transaction from section 2(a)(1)(D) of this title), if the Commission determines that the exemption would be consistent with the public interest.

[10] HOUSE CONF. REPORT NO. 102–978, 1992 U.S.C.C.A.N. 3179, 3213 (''4(c) Conf. Report'').

either case to be cleared by OCC in its capacity as a securities clearing agency, as discussed above, may foster both financial innovation and competition. In accordance with the Memorandum of Understanding entered into between the CFTC and the SEC on March 11, 2008, and in particular the addendum thereto concerning *Principles Governing the Review of Novel Derivative Products*, the Commission believes that novel derivative products that implicate areas of overlapping regulatory concern should be permitted to trade in either or both a CFTC- or SEC-regulated environment, in a manner consistent with laws and regulations (including the appropriate use of all available exemptive and interpretive authority). The CFTC is requesting comment on whether it should exempt Options and Security Futures on Gold and Silver Products, as described above, that are traded on a national securities exchange or a DCM, respectively, and cleared through OCC in its capacity as a registered securities clearing agency, from the CEA and the Commission's regulations thereunder, to the extent necessary to permit them to be so traded and cleared.

In proposing this exemption, the CFTC need not—and does not—find that Options on the Gold and Silver Products are (or are not) options subject to the CEA, or find that Security Futures on the Gold and Silver Products are (or are not) security futures as defined in Section 1a(31) of the CEA.[11] During the legislative process leading to the enactment of Section 4(c) of the CEA, the House-Senate Conference Committee noted that:

> The Conferees do not intend that the exercise of exemptive authority by the Commission would require any determination beforehand that the agreement, instrument, or transaction for which an exemption is sought is subject to the Act. Rather, this provision provides flexibility for the Commission to provide legal certainty to novel instruments where the determination as to jurisdiction is not straightforward. Rather than making a finding as to whether a product is or is not a futures contract, the Commission in appropriate cases may proceed directly to issuing an exemption.[12]

The Options and Security Futures on Gold and Silver Products described above are ''novel instruments.'' Given their potential usefulness to the market, however, the Commission believes that this may be an appropriate case for issuing an exemption without making a finding as to the nature of these particular instruments.

Section 4(c)(2) provides that the Commission may grant exemptions only when it determines: that the requirements for which an exemption is being provided should not be applied to the agreements, contracts or transactions at issue, and the exemption is consistent with the public interest and the purposes of the CEA; that the agreements, contracts or transactions will be entered into solely between appropriate persons; and that the exemption will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory responsibilities under the CEA.[13]

The purposes of the CEA include ''promot[ing] responsible innovation and fair competition among boards of trade, other markets and market participants.''[14] It may be consistent with these and the other purposes of the CEA, with the public interest, with the CFTC–SEC Memorandum of Understanding of March 11, 2008, and with the addendum thereto, for the mode of trading and clearing the Options and Security Futures on Gold and Silver Products—whether the mode applicable to options on securities or commodities, or to security futures or futures—to be determined by competitive market forces. Accordingly, the CFTC is requesting comment as to whether this exemption from the requirements of the CEA and regulations thereunder should be granted in the context of these transactions.

Section 4(c)(3) includes within the term ''appropriate persons'' a number of specified categories of persons, and also in subparagraph (K) thereof ''such other persons that the Commission determines to be appropriate in light of * * * the applicability of appropriate regulatory protections.'' National securities exchanges and OCC, as well as their members who will intermediate Options on Gold and Silver Products, are subject to extensive and detailed regulation by the SEC under the '34 Act. Similarly, DCMs and OCC, as well as their members who will intermediate Security Futures on Gold and Silver Products, are subject to regulation by the SEC and CFTC. The CFTC is requesting comment as to whether all persons trading Options and Security Futures on Gold and Silver Products on national securities exchanges and DCMs, respectively, and clearing such products on OCC, are appropriate persons.

In light of the above, the Commission also is requesting comment as to whether this exemption will interfere with its ability to discharge its regulatory responsibilities under the CEA or with the self-regulatory duties of any contract market or derivatives transaction execution facility.

III. Request for Comment

The Commission requests comment on all aspects of the issues presented by this proposed order.

IV. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'')[15] imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The proposed exemptive order would not, if approved, require a new collection of information from any entities that would be subject to the proposed order.

B. Cost-Benefit Analysis

Section 15(a) of the CEA,[16] as amended by Section 119 of the Commodity Futures Modernization Act of 2000, requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. By its terms, Section 15(a) as amended does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, Section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public;

[11] 7 U.S.C. 1a(31).

[12] 4(c) Conf. Report at 3214–3215.

[13] Section 4(c)(2) of the CEA, 7 U.S.C. 6(c)(2), provides in full that: The Commission shall not grant any exemption under paragraph (1) from any of the requirements of subsection (a) of this section unless the Commission determines that—

(A) the requirement should not be applied to the agreement, contract, or transaction for which the exemption is sought and that the exemption would be consistent with the public interest and the purposes of this Act; and

(B) the agreement, contract, or transaction—

(i) will be entered into solely between appropriate persons; and

(ii) will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory duties under this Act.

[14] CEA 3(b), 7 U.S.C. 5(b). *See also* CEA 4(c)(1), 7 U.S.C. 6(c)(1) (purpose of exemptions is ''to promote responsible economic or financial innovation and fair competition.'').

[15] 44 U.S.C. 3507(d).

[16] 7 U.S.C. 19(a).

efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

The Commission is considering the costs and benefits of this proposed order in light of the specific provisions of Section 15(a) of the CEA, as follows:

1. *Protection of market participants and the public.* National securities exchanges, DCMs, OCC and their members who would intermediate the above-described Options and Security Futures on Gold and Silver Products are subject to extensive regulatory oversight.

2. *Efficiency, competition, and financial integrity.* The proposed exemption may enhance market efficiency and competition since it could encourage potential trading of Options and Security Futures on Gold and Silver Products through modes other than those normally applicable to designated contract markets or derivatives transaction execution facilities. Financial integrity will not be affected since the Options and Security Futures on Gold and Silver Products will be cleared by OCC, a DCO and SEC-registered clearing agency, and intermediated by SEC-registered broker-dealers.

3. *Price discovery.* Price discovery may be enhanced through market competition.

4. *Sound risk management practices.* The Options and Security Futures on Gold and Silver Products will be subject to OCC's current risk-management practices including its margining system.

5. *Other public interest considerations.* The proposed exemption may encourage development of derivative products through market competition without unnecessary regulatory burden.

After considering these factors, the Commission has determined to seek comment on the proposed order as discussed above. The Commission invites public comment on its application of the cost-benefit provision.

Issued in Washington, DC, on November 5, 2008 by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E8–26815 Filed 11–10–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Defense Policy Board Advisory Committee

AGENCY: Department of Defense, Defense Policy Board Advisory Committee.

ACTION: Notice.

SUMMARY: The Defense Policy Board Advisory Committee will meet in closed session on December 1, 2008 from 0800 hrs until 1730 hrs and on December 2, 2008 from 0800 hrs until 1130 hrs at the Pentagon.

The purpose of the meeting is to provide the Secretary of Defense, Deputy Secretary of Defense and Under Secretary of Defense for Policy with independent, informed advice on major matters of defense policy. The Board will hold classified discussions on national security matters.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended [5 U.S.C. App II (1982)], it has been determined that this meeting concerns matters listed in 5 U.S.C. 552B(c)(1)(1982), and that accordingly this meeting will be closed to the public.

Dated: November 4, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–26760 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2008–OS–0139]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to amend a system of records notice.

SUMMARY: The Office of the Secretary of Defense is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record systems being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: November 4, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DPR 36

SYSTEM NAME:

Defense Integrated Military Human Resources System (DIMHRS) Records (September 30, 2008, 73 FR 56807).

CHANGES:

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete ''mother's maiden name'' from first paragraph.

* * * * *

DPR 36

SYSTEM NAME:

Defense Integrated Military Human Resources System (DIMHRS) Records.

SYSTEM LOCATION:

Primary Location Corporate Data Center, Defense Enterprise Computing Center Ogden, 7879 Wardleigh Road, Hill AFB, UT 84056–5996.

Decentralized segments are located at Department of Defense (DoD) activities worldwide. Official mailing addresses can be obtained from the appropriate Service point of contact found in the ''Notification procedure'' or ''Record Access'' sections of this proposed system of records notice.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members of the United States Army, Navy, Air Force and Marines to include: Active Duty, National Guard, Reserve, Retired and former military personnel, and Coast Guard personnel when operating as a military service under the Department of the Navy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personal Information: Individual's name, rank/grade, address, date of birth, eye color, height, weight, place of birth, Social Security Number (SSN), and similar personal identifiers for beneficiary/dependant purposes; driver's license number, security level, office location, assigned user name and security questions, local and home of record addresses, phone numbers and emergency contact information.

Personnel Information: performance plans, evaluation and review history; enrollment, participation, status and outcome information for Personnel Programs; service qualification and performance measures; types of orders; accomplishments, skills and competencies; career preferences; contract information related to Oath of Office, enlistment and re-enlistment; retirement and separation information; retirement points including information necessary to determine retirement pay; benefits eligibility, enrollment, designations and status information; Uniform Code of Military Justice (UCMJ) Actions summarizing court martial, non-judicial punishments, and similar or related documents. Circumstances of an incident the member was involved in and whether he or she is in an injured, wounded, seriously wounded, or ill duty status from the incident.

Duty related information: duty station, employment and job related information and history; deployment information; work title, work address and related work contact information (e.g., phone and fax numbers, E-mail address), supervisor's name and related contact information.

Education and training: high school graduation date and location; highest level of education; other education, training and school information including courses and training completion.

Pay Entitlement and Allowances: pay information including earnings and allowances, additional pay (bonuses, special, and incentive pays); payroll computation, balances and history with associated accounting elements; leave balances and leave history.

Deductions from Pay: tax information (federal, state and local) based on withholding options, payroll deductions, garnishments; savings bond information including designated owner, deductions, and purchase dates; thrift savings plan participation.

Other pay-related information: direct deposit information including financial institution name, routing number and account information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113 note, Secretary of Defense; 10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 8013, Secretary of the Air Force; 14 U.S.C. 5 and 92, Coast Guard; 37 U.S.C., Pay and Allowances of the Uniformed Services; and E.O. 9397 (SSN).

PURPOSE(S):

Provide a fully integrated military personnel and pay capability for all Components of the Military Services of the Department of Defense. Additionally, DIMHRS will provide the Military Services and their components the capability to effectively manage their members during peacetime, war, and through mobilization and demobilization. In addition, it will be used as a management tool for decisions made within the Department of Defense.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To officials and employees of the Department of Health and Human Services, and Selective Service Administration in the performance of their official duties related to eligibility, notification, and assistance in obtaining benefits for which members, former members or retiree may be eligible.

To officials and employees of the Department of Veterans Affairs in the performance of their official duties related to approved research projects, and for processing and adjudicating claims, determining eligibility, notification, and assistance in obtaining benefits and medical care for which members, former members, retiree and family members/annuitants may be eligible.

To the Department of Veterans Affairs to provide information regarding a servicemember's record or family member for the purposes of supporting eligibility processing for the Servicemember's Group Life Insurance program.

To state and local agencies in the performance of their official duties related to verification of status for determination of eligibility for Veterans Bonuses and other benefits and entitlements.

To officials and employees of the American Red Cross in the performance of their duties relating to the assistance of the members and their dependents and relatives, or related to assistance previously furnished such individuals, without regard to whether the individual assisted or his/her sponsor continues to be a member of the Military Service. Access will be limited to those portions of the member's record required to effectively assist the member.

To the U.S. Citizenship and Immigration Services for use in making alien admission and naturalization inquiries.

To the Social Security Administration to obtain or verify Social Security Numbers or to substantiate applicant's credit for social security compensation.

To officials and employees of the Office of the Sergeant at Arms of the United States House of Representatives in the performance of their official duties related to the verification of the active duty military service of Members of Congress. Access is limited to those portions of the member's record required to verify time in service.

To the widow or widower, dependent, or next-of-kin of deceased members to settle the affairs of the deceased member. The categories of individuals listed will have to verify relationship by providing a birth certificate, marriage license, death certificate, or court document as requested/required to prove they are who they say they are.

To governmental agencies for the conduct of computer matching agreements for the purpose(s) of determining eligibility for Federal benefit programs, to determine compliance with benefit program requirements and to recover improper payments or delinquent debts under a federal benefit program.

To officials of the U.S. Coast Guard (USCG) for the purpose of creating service records for current USCG members that had prior Military Service.

To Federal and state licensing authorities and civilian certification boards, committees and/or ecclesiastical endorsing organizations for the purposes of professional credentialing (licensing and certification) of lawyers, chaplains and health professionals.

To Federal agencies such as the National Academy of Sciences, for the purposes of conducting personnel and/

or health-related research in the interest of the Federal government and the public. When not considered mandatory, the names and other identifying data will be eliminated from records used for such research studies.

To the officials and employees of the Department of Labor in the performance of their official duties related to employment and compensation.

The ''Blanket Routine Uses'' set forth at the beginning of DoD's compilation of System of Records Notices apply to this system.

Note: Disclosure to consumer reporting agencies: Disclosures pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to 'consumer reporting agencies' as defined in the Fair Credit Reporting Act (14 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal government, typically to provide an incentive for debtors to repay delinquent Federal government debts by making these debts part of their credit records.

The disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security Number); the amount, status, and history of the claim; and the agency or program under which the claim arose for the sole purpose of allowing the consumer reporting agency to prepare a commercial credit report.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Individual's name, Social Security Number (SSN), and date of birth.

SAFEGUARDS:

DIMHRS automated data is maintained in controlled government facilities. Physical entry is restricted by the use of locks, guards, and is accessible only to authorized personnel with a need-to-know. Access to personal data is limited to person(s) responsible for maintaining and servicing DIMHRS data in performance of their official duties and who are properly trained, screened and cleared for a need-to-know. Access to personal data is further restricted by the use of Common Access Card (CAC) and/or strong password, which are changed periodically according to DoD security policy.

RETENTION AND DISPOSAL:

Disposition pending. Until the National Archives and Records Administration has approved the retention and disposal of these records, treat them as permanent.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of the Under Secretary of Defense, Personnel and Readiness, Information Management, 4040 Fairfax Drive, Arlington, VA 22203–1613.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the appropriate address below.

Navy Records—Navy Personnel Command, Records Management and Policy, PERS 312E, 5720 Integrity Drive, Millington, TN 38055–3120.

Marine Corps Records—Commandant of the Marine Corps, Code MMSB–12, 2008 Elliott Road, Quantico, VA 22134–5030.

Army Records—U.S. Army Human Resources Command, Attn: AHRC-PAV-V, 1 Reserve Way, St. Louis, MO 63132–5200.

Air Force Records—Air Force Personnel Center, HQ AFPC/DPSSRP, 550 C Street West, Suite 19, Randolph AFB, TX 78150–4721.

Coast Guard Records—Commander, CGPC-adm-3, USCG Personnel Command, 4200 Wilson Blvd., Suite 1100, Arlington, VA 22203–1804.

Requests should contain individual's legal name, Social Security Number (SSN), and date of birth.

RECORD ACCESS PROCEDURES:

Individuals seeking written access to information about themselves contained in this system of records should address written inquiries to the appropriate address below.

Navy Records—Navy Personnel Command, Records Management and Policy, PERS 312E, 5720 Integrity Drive, Millington, TN 38055–3120.

Marine Corps Records—Commandant of the Marine Corps, Code MMSB–12, 2008 Elliott Road, Quantico, VA 22134–5030.

Army Records—U.S. Army Human Resources Command, Attn: AHRC-PAV-V, 1 Reserve Way, St. Louis, MO 63132–5200.

Air Force Records—Air Force Personnel Center, HQ AFPC/DPSSRP, 550 C Street West, Suite 19, Randolph AFB, TX 78150–4721.

Coast Guard Records—Commander, CGPC-adm-3, USCG Personnel Command, 4200 Wilson Blvd., Suite 1100, Arlington, VA 22203–1804.

Requests should contain individual's legal name, Social Security Number (SSN), and date of birth.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing information about themselves and for contesting contents and appealing initial agency determinations are published in Administrative Instruction 81; 32 CFR part 311; or may be obtained from the Privacy Act Office, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

RECORD SOURCE CATEGORIES:

Data contained in this system is collected from the individual and DoD Military Services Human Resource Offices.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26745 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2008–OS–0135]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to add a new system of records.

SUMMARY: The Office of the Secretary of Defense is adding a new system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on October, 24, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of

Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DAU 07

SYSTEM NAME:

Acquisition Community Connection (ACC) Members Records.

SYSTEM LOCATION:

Defense Acquisition University, DAU–ELTC, 9820 Belvoir Road, Ft. Belvoir, Virginia 22060–5565.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD personnel (civilian and military), civilian employees of other Federal Agencies, and members of supporting defense industries who have requested accounts for the Acquisition Community Connection (ACC).

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, e-mail address, organization, phone number, and biographic information such as expertise, background, and education.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness and DoD Instruction 5000.57, Defense Acquisition University.

PURPOSE(S):

To focus on acquisition-related topics and disciplines accessed by communities relating to contracting, logistics, program management, business management, cost estimating, facilities engineering, financial management, life cycle logistics, Science and Technology management, production/quality/manufacturing, software acquisition management, systems engineering, test and evaluation across DoD and the Federal Government, as well with Department of Defense contractors. Further information on current communities can be found at *https://acc.dau.mil.* The collection and use of names on this site supports verification during the registration process and enables members to interact; share resources, ideas and experiences to support job performance; and to avoid duplication of professional effort. Further information on current communities can be found at *https://acc.dau.mil.*

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The DoD ''Blanket Routine Uses'' set forth at the beginning of OSD's compilation of systems of records notices applies to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Retrieved by individual's name.

SAFEGUARDS:

The system and associated database is maintained within the Defense Acquisition University's IT Network Facility on Ft. Belvoir, Virginia. Physical access is controlled by approved physical security methods. The requested data is voluntary and users consent to share their information with other contact.

RETENTION AND DISPOSAL:

Records are destroyed when superseded or obsolete. Records are electronically deleted; records do not exist on paper.

SYSTEM MANAGER(S) AND ADDRESS:

Acquisition Community Connection Program Manager, Defense Acquisition University, 9820 Belvoir Road, Ft. Belvoir, VA 22060–5565.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in the system should address written inquiries to Defense Acquisition University, Acquisition Community Connection Program Manager, 9820 Belvoir Road, Ft. Belvoir, VA 22060–5565.

Request should contain full name, e-mail address, phone number and organization, and signature. Request should also refer to the name and number of this Privacy Act System of Record Notice.

RECORD ACCESS PROCEDURES:

Individuals seeking to access information about themselves contained in the system should address written inquiries to the OSD/JS FOIA Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155.

The request should refer to the name and number of this Privacy Act System of Record Notice; contain full name, e-mail address, phone number and organization, and signature.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26746 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2008–OS–0131]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Office of the Secretary of Defense is proposing to alter a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008, unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on October 21, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DTIC 01

SYSTEM NAME:

Defense User Registration System (April 25, 2005, 70 FR 21181).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Defense User Registration System (DURS) Records.''

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''DoD and other U.S. Federal Government agency military and civilian personnel and their contractors; researchers of colleges or universities funded by DoD or other U.S. Federal Government agencies; students and employees of specifically qualifying educational institutions, Groups, and Programs, e.g., Historically Black Colleges, Universities, and Minority Institutions (HBCU/MI), Hispanic Serving Institutions (HSIs), and University Research Support (URS); awardees under the Multidisciplinary University Research Initiative (MURI); awardees and researchers eligible for awards under the Defense Experimental Program to Stimulate Competitive Research (DEPSCOR); designated officials and employees of foreign embassies; and members of Small Business Innovative Research (SBIR) Organizations/Groups.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Information relating to registration requests by individuals seeking access to DTIC-owned or controlled computers, databases, products, and/or services. The records contain the individual's name; organization/company mailing address/physical location; registrants' USERID; password/reset questions; organization/company telephone number(s); access eligibility; dissemination/distribution group codes; and personal and facility security clearance level(s). The records also contain the government approving official's name, office phone number, and e-mail address; dates of registration's activation, and the projected date of expiration. Where applicable, the records contain contract number(s), contract expiration date(s), and the Military Critical Technical Data Agreement (MCTDA) Certification Number. Only DoD employees requesting registration are required to submit their SSNs via encryption to DMDC (Defense Manpower Data Center) to confirm their status as DoD employees. The SSN is not viewed, stored, nor accessible by DTIC.''

* * * * *

AUTHORITY:

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulation; E.O. 12958, Classified National Security Information; DOD 5200.1–R, Information Security Program; Defense Information Systems Agency Instruction 240–110–8, Information Security Program; and E.O. 9397 (SSN).''

PURPOSE(S):

Delete entry and replace with ''The purpose of this system of records is to collect, validate eligibility, and maintain an official registry file that identifies individuals and organizations who apply for, and are granted, access privileges to DTIC products, services and electronic information systems.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''Individual name, e-mail address, and security clearance level.''

SAFEGUARDS:

Delete entry and replace with ''Records are maintained in secure, limited access, or monitored areas. Database is monitored and access is password protected. Physical entry by unauthorized persons is restricted through the use of locks, guards, passwords, or other administrative procedures. Archived data is stored on discs, or magnetic tapes, which are kept in a locked or controlled access area. Access to personal information is limited to those individuals who require the records to perform their official assigned duties.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Electronic records are to be deleted when/if DTIC determines they are no longer needed for administrative, audit, legal or operational purposes. Approved disposal methods for electronic records and media include overwriting, degaussing, erasing, disintegration, pulverization, burning, melting, incineration, shredding or sanding.''

* * * * *

DTIC 01

SYSTEM NAME:

Defense User Registration System (DURS) Records.

SYSTEM LOCATION:

Defense Technical Information Center (DTIC), Directorate of User Services, Marketing and Registration Division, *ATTN:* DTIC–BC (Registration), 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060–6218.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD and other U.S. Federal Government agency military and civilian personnel and their contractors; researchers of colleges or universities funded by DoD or other U.S. Federal Government agencies; students and employees of specifically qualifying educational institutions, Groups, and Programs, e.g., Historically Black Colleges, Universities, and Minority Institutions (HBCU/MI), Hispanic Serving Institutions (HSIs), and University Research Support (URS); awardees under the Multidisciplinary University Research Initiative (MURI); awardees and researchers eligible for awards under the Defense Experimental Program to Stimulate Competitive Research (DEPSCOR); designated officials and employees of foreign embassies; and members of Small Business Innovative Research (SBIR) Organizations/Groups.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information relating to registration requests by individuals seeking access to DTIC-owned or controlled computers, databases, products, and/or services. The records contain the individual's name; organization/company mailing address/physical location; registrants' USERID; password/reset questions; organization/company telephone number(s); access eligibility; dissemination/distribution group codes; and personal and facility security clearance level(s). The records also contain the government approving official's name, office phone number, and e-mail address; dates of registration's activation, and the projected date of expiration. Where applicable, the records contain contract number(s), contract expiration date(s), and the Military Critical Technical Data Agreement (MCTDA) Certification Number. Only DoD employees requesting registration are required to submit their SSNs via encryption to DMDC (Defense Manpower Data Center) to confirm their status as DoD employees. The SSN is not viewed, stored, nor accessible by DTIC.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulation; E.O. 12958, Classified National Security Information; DOD 5200.1–R, Information Security Program; Defense Information Systems Agency Instruction 240–110–8, Information Security Program; and E.O. 9397 (SSN).

PURPOSE(S):

To collect, validate eligibility, and maintain an official registry file that identifies individuals and organizations who apply for, and are granted, access privileges to DTIC products, services and electronic information systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 552a(b)(3) as follows:

The DoD ''Blanket Routine Uses'' set forth at the beginning of OSD's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Individual name, e-mail address, and security clearance level.

SAFEGUARDS:

Records are maintained in secure, limited access, or monitored areas. Database is monitored and access is password protected. Physical entry by unauthorized persons is restricted through the use of locks, guards, passwords, or other administrative procedures. Archived data is stored on discs, or magnetic tapes, which are kept in a locked or controlled access area. Access to personal information is limited to those individuals who require the records to perform their official assigned duties.

RETENTION AND DISPOSAL:

Electronic records are to be deleted when/if DTIC determines they are no longer needed for administrative, audit, legal or operational purposes. Approved disposal methods for electronic records and media include overwriting, degaussing, erasing, disintegration, pulverization, burning, melting, incineration, shredding or sanding.

SYSTEM MANAGER(S) AND ADDRESS:

The Chief, Marketing and Registration Division, DTIC–BC, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060–6218.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves may address their inquiries to Defense Technical Information Center; ATTN: DTIC–BC (Registration Team), 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060–6218.

Requests should contain the individual's full name, Social Security Number, telephone number, street address, and e-mail address.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system of records should address written inquires to the Privacy Act Officer, Defense Technical Information Center, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060–6218.

Requests should contain the individual's full name, Social Security Number, telephone number, street address, and e-mail address.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is obtained from security personnel and individuals applying for access to DTIC controlled access documents, information systems, and/or services.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26749 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008-OS–0136]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Office of the Secretary of Defense is altering a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Office of the Secretary of Defense, Privacy Act Coordinator, Records Management Section, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r), of the Privacy Act of 1974, as amended, was submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DHA 06

SYSTEM NAME:

USTF Managed Care System (August 23, 1995, 60 FR 43775).

Changes:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Designated Provider Managed Care System Records.''

SYSTEM LOCATION:

Delete entry and replace with ''Primary location: Office of the Assistant Secretary of Defense (Health Affairs), Deputy Director (TRICARE Management Activity), Chief, Health Plan Operations, Deputy Chief TRICARE Operations, Director Program Operations, Designated Provider Program Manager, Skyline Five, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3201.

SECONDARY LOCATIONS:

Designated Provider Data Contract Site: Apptis, Inc., 5201 Leesburg Pike Skyline Three, Suite 600, Falls Church, VA 22741–3206.

Subcontractors: Ingenix, 12125 Technology Drive, Eden Prairie, MN 55344–7302; DefenseWeb Technologies, 4150 Mission Blvd., Suite 220, San Diego, CA 92109–5054.

Designated Provider Management Office Sites: Martin's Point Health Care, 331 Veranda Street, Portland, ME 04103–5040; Brighton Marine Health Center, 77 Warren Street, Boston, MA 02135–9862; St. Vincent Catholic Medical Centers of New York, 450 West 33rd Street, New York, NY 10001–2603; Johns Hopkins Medical Services Corporation, 6704 Curtis Court, Glen Burnie, MD 21060–6406; CHRISTUS Health, 2600 North Loop West, Houston, TX 77092–8914; Pacific Medical Clinics, 1200 12th Avenue South, Seattle, WA 98144–2790.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Individuals eligible to participate in, and who have elected to enroll in the Uniformed Services Family Health Plan (USFHP) of the Department of Defense Military Health Services of Managed Care System.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Enrollment Records: Electronic files containing beneficiary ID, name, Social Security Number (SSN), date of birth, gender, sponsor status (active duty or retired), relationship to sponsor, sponsor pay grade, sponsor name and Social Security Number (SSN), state/country, zip code, and program enrollment information (i.e., date of enrollment, expiration of enrollment, program enrolled in, etc.).

Management Clinical Data Records: Electronic files containing Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Managed Care System, System identifier, beneficiary ID, name, Social Security Number (SSN), other demographics (i.e., county, state, zip code, coverage area for Uniformed Services Family Health Plan, healthcare services, healthcare provider, and financial information (e.g., Diagnosis-Related Groups and uniformed service beneficiaries cost share).

Medicare Claims Records: Electronic files containing claim identifiers, beneficiary ID, county, state, zip code, healthcare services, healthcare provider, and cost of healthcare and procedure retained for two years for analysis of cost trends.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''DoD 6025.18–R, DoD Health Information Privacy Regulation; Public Law 104–201, § 722–726; Health Insurance Portability and Accountability Act of 1996 (HIPAA); 10 U.S.C. 1102, Confidentiality of Medical Quality Assurance Records: Qualified Immunity for Participants; and E.O. 9397 (SSN).''

PURPOSE(S):

Delete entry and replace with ''The system is used to administer the Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Managed Care System. It identifies eligible beneficiaries enrolled in Uniformed Services Family Health Plan managed care programs and records healthcare services provided and payments made on behalf of eligible uniformed services health beneficiaries. Additional management functions enable DoD Healthcare Officials to use information in the system at individual and aggregate levels to monitor quantity and type of healthcare provided and to analyze and study the cost effectiveness of the Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Managed Care System.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with ''Disclosures to Center for Medicare and Medicaid Services (CMS), to detect duplicate or overlapping payments made by Medicare.

Disclosures to National Oceanic Service, United States Public Health Service, United States Coast Guard, and National Oceanic and Atmospheric Administration to track services provided to their uniformed service personnel and beneficiaries.

The 'Blanket Routine Uses' set forth at the beginning of OSD's compilation of systems of records notices also apply to this system.

Note: This system of records contains individually identifiable health information. The DoD 6025.18–R, ''DoD Health Information Privacy Regulation'' issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information and may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.''

STORAGE:

Delete entry and replace with ''Electronic storage media and paper records in file folders.''

RETRIEVABILITY:

Delete entry and replace with ''Patient or sponsor's surname and/or Social Security Number (SSN).''

SAFEGUARDS:

Delete entry and replace with ''Records are maintained in a controlled area accessible only to authorized personnel. Entry to this area is restricted to personnel with a valid requirement and authorization to enter. Physical entry is restricted by the use of a cipher lock on the entrance to the room. Personal data maintained at the back-up site is stored in a secure area. Access to personal data records is restricted to those individuals who require the records in the performance of official duties and to those records that are the subject of official duties. Access is restricted by passwords that are changed every ninety days.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Paper records are closed out at the end of the calendar year in which finalized and held six additional years and then destroyed. Where hard copy records have been converted to electronic, microfilm, imaging, or optical formats, the hard copy record is destroyed and the electronic, microfilm, imaging, or optical format is kept by the contractor for six years after claim is processed to completion and then destroyed. Storage media containing data with personal identifiers will be erased (degaussed) after the inactive record retention. Paper records are forwarded to the National Records Archives, and are maintained.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Designated Program Manager, TRICARE Management Activity, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3238.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Deputy Chief, TRICARE Operations, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3238.

The request should contain the full name of the patient and sponsor, sponsor's Social Security Number (SSN), patient's date of birth, Defense Enrollment/Eligibility Reporting System dependent suffix, gender, treatment

facility(ies), and calendar year(s) of interest.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the OSD/JS FOIA Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155.

The request should contain the full names of the patient and sponsor, sponsor's Social Security Number (SSN), patient's date of birth, Defense Enrollment/Eligibility Reporting System dependent suffix, gender, treatment facility(ies), and calendar year(s) of interest.''

* * * * *

DHA 06

SYSTEM NAME:

Designated Provider Managed Care System Records.

SYSTEM LOCATION:

Primary location: Office of the Assistant Secretary of Defense (Health Affairs), Deputy Director (TRICARE Management Activity), Chief, Health Plan Operations, Deputy Chief TRICARE Operations, Director Program Operations, Designated Provider Program Manager, Skyline Five, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3201.

Secondary locations: Designated Provider Data Contract Site: Apptis, Inc., 5201 Leesburg Pike Skyline Three, Suite 600, Falls Church, VA 22741–3206.

Subcontractors: Ingenix, 12125 Technology Drive, Eden Prairie, MN 55344–7302; DefenseWeb Technologies, 4150 Mission Blvd, Suite 220, San Diego, CA 92109–5054.

Designated Provider Management Office Sites: Martin's Point Health Care, 331 Veranda Street, Portland, ME 04103–5040; Brighton Marine Health Center, 77 Warren Street, Boston, MA 02135–9862; St. Vincent Catholic Medical Centers of New York, 450 West 33rd Street, New York, NY 10001–2603; Johns Hopkins Medical Services Corporation, 6704 Curtis Court, Glen Burnie, MD 21060–6406; CHRISTUS Health, 2600 North Loop West, Houston, TX 77092–8914; Pacific Medical Clinics, 1200 12th Avenue South, Seattle, WA 98144–2790.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals eligible to participate in, and who have elected to enroll in the Uniformed Services Family Health Plan (USFHP) of the Department of Defense Military Health Services of Manage Care System.

CATEGORIES OF RECORDS IN THE SYSTEM:

Enrollment Records: Electronic files containing beneficiary ID, name, Social Security Number (SSN), date of birth, gender, sponsor status (active duty or retired), relationship to sponsor, sponsor pay grade, sponsor name and Social Security Number (SSN), state/country, zip code, and program enrollment information (i.e., date of enrollment, expiration of enrollment, program enrolled in, etc.).

Management Clinical Data Records: Electronic files containing Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Manage Care System, System identifier, beneficiary ID, name, Social Security Number (SSN), other demographics (i.e., county, state, zip code, coverage area for Uniformed Services Family Health Plan, healthcare services, healthcare provider, and financial information (e.g., Diagnosis-Related Groups and uniformed service beneficiaries cost share.)

Medicare Claims Records: Electronic files containing claim identifiers, beneficiary ID, county, state, zip code, healthcare services, healthcare provider, and cost of healthcare and procedure retained for two years for analysis of cost trends.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

DoD 6025.18–R, DoD Health Information Privacy Regulation; Public Law 104–201, § 722–726; Health Insurance Portability and Accountability Act of 1996 (HIPAA); 10 U.S.C. 1102, Confidentiality of Medical Quality Assurance Records: Qualified Immunity for Participants; and E.O. 9397 (SSN).

PURPOSE(S):

The system is used to administer the Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Managed Care System. It identifies eligible beneficiaries enrolled in Uniformed Services Family Health Plan managed care programs and records healthcare services provided and payments made on behalf of eligible uniformed services health beneficiaries. Additional management functions enable DoD Healthcare Officials to use information in the system at individual and aggregate levels to monitor quantity and type of healthcare provided and to analyze and study the cost effectiveness of the Uniformed Services Family Health Plan of the Department of Defense Military Health Services of Managed Care System.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosures to Center for Medicare and Medicaid Services (CMS), to detect duplicate or overlapping payments made by Medicare.

Disclosures to National Oceanic Service, United States Public Health Service, United States Coast Guard, and National Oceanic and Atmospheric Administration to track services provided to their uniformed service personnel and beneficiaries.

The ''Blanket Routine Uses'' set forth at the beginning of OSD's compilation of systems of records notices also apply to this system.

Note: This system of records contains individually identifiable health information. The DoD 6025.18–R, ''DoD Health Information Privacy Regulation'' issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information and may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media and paper records in file folders.

RETRIEVABILITY:

Patient or sponsor's surname and/or Social Security Number (SSN).

SAFEGUARDS:

Records are maintained in a controlled area accessible only to authorized personnel. Entry to this area is restricted to personnel with a valid requirement and authorization to enter. Physical entry is restricted by the use of a cipher lock on the entrance to the room. Personal data maintained at the back-up site is stored in a secure area. Access to personal data records is restricted to those individuals who require the records in the performance of official duties and to those records that are the subject of official duties. Access is restricted by passwords that are changed every ninety days.

RETENTION AND DISPOSAL:

Paper records are closed out at the end of the calendar year in which finalized and held six additional years and then destroyed. Where hard copy records have been converted to electronic, microfilm, imaging, or optical formats, the hard copy record is destroyed and the electronic, microfilm, imaging, or optical format is kept by the

contractor for six years after claim is processed to completion and then destroyed. Storage media containing data with personal identifiers will be erased (degaussed) after the inactive record retention. Paper records are forwarded to the National Records Archives, and are maintained.

SYSTEM MANAGER(S) AND ADDRESS:

Designated Program Manager, TRICARE Management Activity, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3238.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Deputy Chief, TRICARE Operations, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3238.

The request should contain the full name of the patient and sponsor, sponsor's Social Security Number (SSN), patient's date of birth, Defense Enrollment/Eligibility Reporting System dependent suffix, gender, treatment facility(ies), and calendar year(s) of interest.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the OSD/JS FOIA Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155.

The request should contain the full names of the patient and sponsor, sponsor's Social Security Number (SSN), patient's date of birth, Defense Enrollment/Eligibility Reporting System dependent suffix, gender, treatment facility(ies), and calendar year(s) of interest.

CONTESTING RECORD PROCEDURES:

The OSD's rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311, Office of the Secretary of Defense, OSD Privacy Program; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Uniformed Services Family Health Plan enrollment records; medical/hospital information systems, and/or billing systems; eligibility information from the Defense Enrollment/Eligibility Reporting System; claim information from the Center for Medicare and Medicaid; beneficiary information from National Oceanic and Atmospheric Administration; National Oceanic Service; U.S. Coast Guard; and U.S. Public Health Service.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26751 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008–OS–0133]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to amend a system of records notice.

SUMMARY: The Office of the Secretary of Defense is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Office of Freedom of Information, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Cindy Allard at (703) 588–2386.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record systems being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DWHS E04

SYSTEM NAME:

Privacy Act Case Files.

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Washington Headquarters Services records: Freedom of Information Division, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

DoD Educational Activity Records: Department of Defense Education Activity, Privacy Act Office, Executive Services Offices, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''All persons who have requested documents and/or appeals under the provisions of the Privacy Act (PA); and attorneys representing individuals submitting such requests.''

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 552a, The Privacy Act of 1974, as amended; DoD 5400.11–R, Department of Defense Privacy Program; Administrative Instruction 81, Privacy Program; 10 U.S.C. 2164, Department of Defense Domestic Dependent Elementary and Secondary Schools; 20 U.S.C. 921–932, Overseas Defense Dependent's Education; DoD Directive 1342.20 Department of Defense Education Activity and E.O. 9397 (SSN).''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''For Washington Headquarters Services records: OSD/JS Privacy Office, Office of Freedom of Information, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to:

For Washington Headquarters Services records: Chief, OSD/JS Privacy Office, Office of Freedom of Information, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Act Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

Written requests should include the individual's name.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking to access their record should address written inquiries to:

For Washington Headquarters Services records: OSD/JS Freedom of Information Requester Service Center, Office of Freedom of Information, Executive Services Directorate, Washington, Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Act Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

Requests for access must include this System of Record Notice name and number, be in writing, signed, and provide evidence of the requester's identity such as a copy of a photo ID or passport or similar document bearing the requester's signature. Additionally for DoD Education Activity records: if a parent or legal guardian is requesting records pertaining to his or her minor child or ward, he/she must also provide evidence of that relationship. For example, the parent may provide a copy of the child's school enrollment form signed by the parent, or copy of a divorce decree or travel order that includes the child's name, or an order of guardianship, or a declaration stating that he/she is the parent or legal guardian of the minor or incapacitated child.''

* * * * *

DWHS E04

SYSTEM NAME:

Privacy Act Case Files.

SYSTEM LOCATION:

Washington Headquarters Services records: Freedom of Information Division, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

DoD Educational Activity Records: Department of Defense Education Activity, Privacy Act Office, Executive Services Offices, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All persons who have requested documents and/or appeals under the provisions of the Privacy Act (PA); and attorneys representing individuals submitting such requests.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records created or compiled in response to Privacy Act requests and administrative appeals, i.e.; original and copies of requests and administrative appeals; responses to such requests and administrative appeals; all related memoranda, correspondence, notes, and other related or supporting documentation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 552a, The Privacy Act of 1974, as amended; DoD 5400.11–R, Department of Defense Privacy Program; Administrative Instruction 81, Privacy Program; 10 U.S.C. 2164, Department of Defense Domestic Dependent Elementary and Secondary Schools; 20 U.S.C. 921–932, Overseas Defense Dependent's Education; DoD Directive 1342.20 Department of Defense Education Activity and E.O. 9397 (SSN).

PURPOSE(S):

Information is being collected and maintained for the purpose of processing Privacy Act requests and administrative appeals; for participating in litigation regarding agency action on such requests and appeals; and for assisting the Department of Defense in carrying out any other responsibilities under the Privacy Act of 1974.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of OSD's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

By name and/or request number.

SAFEGUARDS:

Records are maintained in security containers with access only to officials whose access is based on requirements of assigned duties. Computer databases are password protected and accessed by individuals who have a need-to-know.

RETENTION AND DISPOSAL:

Responses granting access to all the requested records, destroy 2 years after the date of reply. Responding to requests for nonexistent records; to requesters who provide inadequate descriptions; and to those who fail to pay agency reproduction fees; destroy requests not appealed 2 years after date of reply; destroy appealed requests in accordance with the approved disposition instructions for related subject individual's records or 3 years after final adjudication by the courts, whichever is later. Responses denying access to all or part of the records requested, destroy requests not appealed 5 years after date of reply.

SYSTEM MANAGER(S) AND ADDRESS:

For Washington Headquarters Services records: OSD/JS Privacy Office, Office of Freedom of Information, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to:

For Washington Headquarters Services records: Chief, OSD/JS Privacy Office, Office of Freedom of Information, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Act Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

Written requests should include the individual's name.

RECORD ACCESS PROCEDURES:

Individuals seeking to access their record should address written inquiries to:

For Washington Headquarters Services records: OSD/JS Freedom of

Information Requester Service Center, Office of Freedom of Information, Executive Services Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

For DoD Education Activity records: Department of Defense Education Activity, Privacy Act Office, Executive Services Office, Office of the Chief of Staff, 4040 North Fairfax Drive, Arlington, VA 22203–1634.

Requests for access must include this System of Record Notice name and number, be in writing, signed, and provide evidence of the requester's identity such as a copy of a photo ID or passport or similar document bearing the requester's signature. Additionally for DoD Education Activity records: if a parent or legal guardian is requesting records pertaining to his or her minor child or ward, he/she must also provide evidence of that relationship. For example, the parent may provide a copy of the child's school enrollment form signed by the parent, or copy of a divorce decree or travel order that includes the child's name, or an order of guardianship, or a declaration stating that he/she is the parent or legal guardian of the minor or incapacitated child.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Those individuals who submit initial requests and administrative appeals pursuant to the Privacy Act; the agency records searched in the process of responding to such requests and appeals; Department of Defense personnel assigned to handle such requests and appeals; other agencies or entities that have referred to the Department of Defense requests concerning Department of Defense records, or that have consulted with the Department of Defense regarding the handling of particular requests; and submitters or subjects of records or information that have provided assistance to the Department of Defense in making access or amendment determinations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

During the course of a Privacy Act (PA) action, exempt materials from other systems of records may become part of the case records in this system of records. To the extent that copies of exempt records from those 'other' systems of records are entered into these PA case records, Washington Headquarters Services hereby claims the same exemptions for the records as they have in the original primary systems of records which they are a part.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 311. For additional information contact the system manager.

[FR Doc. E8–26761 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008–OS–0132]

Privacy Act of 1974; Systems of Records

AGENCY: Defense Finance and Accounting Service, DoD.

ACTION: Notice to add a new system of records.

SUMMARY: The Defense Finance and Accounting Service (DFAS) is proposing to add a new system of records notice to its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This Action will be effective without further notice on December 12, 2008, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the FOIA/PA Program Manager, Corporate Communications and Legislative Liaison, Defense Finance and Accounting Service, 6760 E. Irvington Place, Denver, CO 80279–8000.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Krabbenhoft at (303) 676–6045.

SUPPLEMENTARY INFORMATION: The Defense Finance and Accounting Service systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on October 21, 2008, to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated December 12, 2000, 65 FR 239.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

T7335b

SYSTEM NAME:

Electronic Business-Labor and Accounting Report (E-BIZ) Records

SYSTEM LOCATION:

Defense Information Systems Agency (DISA), 701 South Courthouse Road, Arlington, VA 22204–2199.

Defense Enterprise Computing Center (DECC), CDC4, 3990 East Broad Street, Columbus, Ohio 43213–1152.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD civilian employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Social Security Number (SSNs), name, time and attendance information, leave balances, purchase information, disbursements, workcounts, cost allocation, and manpower data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations, Defense Financial Management Regulation (DoDFMR) 7000.14–R, Vol 8; 31 U.S.C. 3512, Executive agency accounting and other financial management reports and plans; 31 U.S.C. 3513, Financial reporting and accounting system and E.O. 9397 (SSN).

PURPOSE(S):

The Defense Finance and Accounting Service (DFAS) is proposing to establish a system or records in support of its core financial management mission. The system will be used as a feeder system that has a suite of business processes that will integrate resource, accounting, financial and other business functions into a comprehensive management information planning system. The data will include budget information, manpower data, performance measures,workload management, time and attendance, labor reporting, work counts, cost accounting, funds control, accounts payable and receivable, general ledger, and financial reporting. It will be used to produce useful, timely and accurate management andfinancial data, allow users to do analysis and reconciliation to ensure data accuracy, provide decision and planning tools for management, and provide timely and accurate financial statements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Department of Defense as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD ''Blanket Routine Uses'' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

By name and/or Social Security Number (SSN).

SAFEGUARDS:

Records are stored in an office building protected by guards, controlled screening, use of visitor registers, electronic access, and/or locks. Access to records is limited to authorized individuals who are properly screened and cleared on a need-to-know basis in the performance of their official duties. Passwords and digital signatures are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system.

RETENTION AND DISPOSAL:

Records are cut off at the end of the payroll year and destroyed after audit or when six years old, whichever is sooner. Records are destroyed by degaussing the electronic media and recycling hardcopy records. The recycled hardcopies are destroyed by shredding, burning, or pulping.

SYSTEM MANAGER(S) AND ADDRESS:

Defense Finance and Accounting Service, E–Biz System Manager, Program Management Office, Building 11, Section 6, 3990 East Broad St, Columbus, Ohio 43213–1152.

NOTIFICATION PROCEDURE:

An individual seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Defense Finance and Accounting Service, Freedom of Information/ Privacy Act Program Manager, Corporate Communications and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

Individuals should furnish full name, Social Security Number (SSN), current address, and telephone number.

RECORD ACCESS PROCEDURES:

An individual seeking access to information about themselves that is contained in this system should address written inquiries to Defense Finance and Accounting Service, Freedom of Information/Privacy Act Program Manager, Corporate Communications and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

Individuals should furnish full name, Social Security Number (SSN), current address, and telephone number.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from Defense Finance and Accounting Service, Freedom of Information/ Privacy Act Program Manager, Corporate Communications and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

RECORD SOURCE CATEGORIES:

Records are obtained from the individual concerned, and DoD Components.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26762 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008–OS–0134]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to amend a system of records.

SUMMARY: The Defense Logistics Agency is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Headquarters, Defense Logistics Agency, *ATTN:* DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S259.05

SYSTEM NAME:

Legal Assistance (August 25, 2006, 71 FR 50396).

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with ''S170.06.''

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Office of the General Counsel, Defense Supply Center Columbus, *ATTN:* DSCC–G, 3990 East Broad Street, Columbus, OH 43213–1199.''

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with ''Correspondence, memoranda, attorney opinions, and similar records accumulated as a result of providing legal advice and assistance to military personnel and their dependents are destroyed 1 year after completion of case except legal instruments withdrawn for use as precedents may be held until no longer needed for reference.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''General Counsel, Defense Supply Center Columbus, *ATTN:* DSCC–G, 3990 East Broad Street, Columbus, OH 43213–1199.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine

whether information about themselves is contained in this system of records should address written inquiries to the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individual must provide full name and date assistance was requested.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individual must provide full name and date assistance was requested.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

* * * * *

S170.06

SYSTEM NAME:

Legal Assistance.

SYSTEM LOCATION:

Office of the General Counsel, Defense Supply Center Columbus, *ATTN:* DSCC–G, 3990 East Broad Street, Columbus, OH 43213–1199.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Authorized military personnel and their dependents who have requested legal advice and/or assistance.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents prepared in response to requests for legal advice and assistance, and the background information supplied by the requester to prepare the documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations.

PURPOSE(S):

Documents are used to provide copies for individuals requesting the assistance, their representative or where otherwise appropriate, members of their immediate families. Documents may also be used as models or examples for preparing future documents.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DOD ''Blanket Routine Uses'' apply to this system of records.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Records may be maintained on paper and on electronic storage media.

RETRIEVABILITY:

Records are retrieved by individual's name.

SAFEGUARDS:

Attorney operating folders are kept in a file cabinet or other storage devices accessible only to authorized personnel of the DSCC Office of Counsel or as determined by the DSCC Counsel.

RETENTION AND DISPOSAL:

Correspondence, memoranda, attorney opinions, and similar records accumulated as a result of providing legal advice and assistance to military personnel and their dependents are destroyed 1 year after completion of case except legal instruments withdrawn for use as precedents may be held until no longer needed for reference.

SYSTEM MANAGER(S) AND ADDRESS:

General Counsel, Defense Supply Center Columbus, *ATTN:* DSCC–G, 3990 East Broad Street, Columbus, OH 43213–1199.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individual must provide full name and date assistance was requested.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about them contained in this system of records should address written inquiries to the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Individual must provide full name and date assistance was requested.

CONTESTING RECORD PROCEDURES:

The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Office, Headquarters Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

RECORD SOURCE CATEGORIES:

Individual requesting legal advice and/or assistance.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26766 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008–OS–0138]

Privacy Act of 1974; Systems of Records

AGENCY: Defense Finance and Accounting Service, DoD.

ACTION: Notice To Add a New System of Records.

SUMMARY: The Defense Finance and Accounting Service (DFAS) is proposing to add a system of records notice to its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the FOIA/PA Program Manager, Corporate Communications and Legislative Liaison, Defense Finance and Accounting Service, 6760 E. Irvington Place, Denver, CO 80279–8000.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Krabbenhoft, 303–676–6045.

SUPPLEMENTARY INFORMATION: The Defense Finance and Accounting Service systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on October 30, 2008, to the House Committee on Government

Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated December 12, 2000, 65 FR 239.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

T–4500

SYSTEM NAME:

Defense Transportation Payment System (DTRS) Records.

SYSTEM LOCATION:

Defense Information Systems Agency, Defense Enterprise Computing Center, Ogden, 8705 Industrial Blvd., Tinker AFB OK 73145–3352.

Defense Finance & Accounting Service (DFAS), Indianapolis, Systems Management Directorate, Vendor Payment System, 8899 E. 56th Street, Indianapolis IN, 46249–0100. Telephone number (317) 510–7789.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

United States Air Force, Army, active, and reserve members, Department of Defense (DoD) civilian employees and other Federal civilian employees paid by appropriated funds, and whose household goods claims are processed by the Defense Finance and Accounting Service.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number (SSN), Electronic Fund Transfer data, address, telephone number and financial payment information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; Department of Defense Financial Management Regulation (DoDFMR) 7000.14–R, Volume 5; 31 U.S.C. 3511, Prescribing Accounting Requirements and Developing Accounting Systems; 31 U.S.C. 3512, Executive agency accounting and other financial management reports and plans; and 31 U.S.C. 3513, Financial Reporting and Accounting System; and E.O. 9397 (SSN).

PURPOSE(S):

This system will be a standard base level entitlement system used for making household goods transportation payments. The system will contain accounting records for funding authority, commitments, and obligations. It will account for and produce monthly financial status reports related to the household goods transportation payments that are made to moving companies/carriers, vendors, United States Air Force, Army, active, and reserve members, Department of Defense civilian employees, and other Federal civilian employees whose transportation payments are processed by the Defense Finance and Accounting Service.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

Name and Social Security Number (SSN).

SAFEGUARDS:

Records are stored in an office building protected by guards, controlled screening, use of visitor registers, electronic access, and/or locks. Access to records is limited to authorized individuals who are properly screened and cleared on a need-to-know basis in the performance of their duties.

Passwords and digital signatures are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system.

RETENTION AND DISPOSAL:

Records are temporary in nature, cut off at the end of the fiscal year and destroyed 6 years and 3 months after cutoff. Records are destroyed by degaussing, burning, or shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Defense Finance and Accounting Service, System Management Directorate, Vendor Payment System, 8899 E. 56th Street, Indianapolis, IN 46249–0100. Telephone number (317) 510–7710.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Defense Finance and Accounting, Freedom of Information/Privacy Act Program Manager, Corporate Communication and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

Individuals should furnish full name, Social Security Number (SSN), current address, and telephone number and provide a reasonable description of the record they are seeking.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquires to Defense Finance and Accounting Service, Freedom of Information/Privacy Act Program Manager, Corporate Communications and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

Individuals should furnish full name, Social Security Number (SSN), current address, and telephone number and provide a reasonable description of the record they are seeking.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from Defense Finance and Accounting Service, Freedom of Information/ Freedom of Information/Privacy Act Program Manager, Corporate Communication and Legislative Liaison, 6760 E. Irvington Place, Denver, CO 80279–8000.

RECORD SOURCE CATEGORIES:

From the individual concerned, DoD Components, and other Federal agencies such as the State Department and Federal Prisons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26768 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2008–OS–0137]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Defense Logistics Agency is proposing to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Headquarters, Defense Logistics Agency, *ATTN:* DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on October 24, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S330.50

SYSTEM NAME:

Reasonable Accommodation Request Records.

SYSTEM LOCATION:

Equal Employment Opportunity Office, Headquarters, Defense Logistics Agency, *ATTN:* DO, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221 and the Equal Employment Opportunity Offices at the DLA Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Defense Logistics Agency employees and applicants with disabilities who have requested reasonable accommodations under The Rehabilitation Act of 1973, as amended.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests for reasonable accommodations; medical documents; notes or records made during consideration of requests; decisions on requests; records made to implement or track decisions on requests.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Rehabilitation Act of 1973, as amended; 29 U.S.C. 791, Employment of Individuals with Disabilities; E.O. 13163, Increasing the Opportunity for Individuals with Disabilities to be Employed in the Federal Government; and E.O. 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation.

PURPOSE(S):

This system is maintained for the purpose of considering, deciding, and implementing requests for reasonable accommodation made by DLA employees and applicants with disabilities. The system documents and tracks requests made to DLA for reasonable accommodation, and action taken by DLA in response to the requests. It also serves as a reference source for inquiries and responses thereto on a ''need-to-know'' basis only. The Disability Program Coordinators (DPC) in each field activity will use these records to develop cumulative records, without individual identifiers, which could include trend and cost analysis, to track performance in regard to the provision of reasonable accommodation by DLA. The DPC will also use these records to develop a qualitative assessment of the local program, to include recommendations for improvement, for submission to the DLA Disability Program Manager (DPM).

On a need-to-know basis, information is provided to DLA supervisors and managers about necessary restrictions on work or duties of the employee and about the necessary accommodations.

Records will be used by DLA to track agency compliance with E.O. 13164 and U.S. Equal Employment Opportunity Commission (EEOC) guidance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records and information contained therein may specifically be disclosed outside DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To first aid and safety personnel, when appropriate, if the disability might require emergency treatment.

To the Department of Labor, in certain circumstances, for workers' compensation claims.

To Federal Government officials charged with the responsibility of investigating the Defense Logistics Agency's compliance with The Rehabilitation Act of 1973, as amended.

To the U.S. Equal Employment Opportunity Commission (EEOC) when requested in connection with an investigation into alleged or possible discriminatory practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures, or other functions vested in the Commission.

To the Office of Personnel Management; Merit System Protection Board; and/or Office of Special Counsel, to provide data without personal identifiers for other federally mandated reporting requirements.

Note: In each of these cases, DLA will determine whether disclosure of the records is compatible with the purpose for which the records were collected.

The DOD ''Blanket Routine Uses'' also apply to this system of record.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on paper and/or on electronic storage media.

RETRIEVABILITY:

Records are retrieved by the individual's name and the date of the request for accommodation or by type of accommodation.

SAFEGUARDS:

Records are maintained in a secure, limited access, or monitored work area. Physical entry by unauthorized persons is restricted by the use of locks, guards, or administrative procedures. Access to personal information is restricted to those who require the records in the performance of their official duties. Access to computer records is further restricted by the use of passwords

which are changed periodically. All personnel whose official duties require access to the information are to have been trained in the proper safeguarding and use of the information, and are to have taken Information Assurance and Privacy Act training.

RETENTION AND DISPOSAL:

General files are destroyed three years after supersession or when no longer needed for reference whichever is later. These include agency-wide and departmental procedures for receiving, processing, and appealing requests for reasonable accommodation by employees and applicants. Files may include, but are not limited to, instructions, directives, notices, forms, timetables and guidelines for requesting, processing and approving requests and for appealing decisions for reasonable accommodation. Also included are records notifying the U.S. Equal Employment Opportunity Commission (EEOC), the agency's collective bargaining representative(s), and the agency's Equal Employment Opportunity office of the agency's reasonable accommodation request and processing procedures as well as modifications to established procedures.

Employee case files are destroyed three years after employee separation from the agency or when all appeals are concluded, whichever is later. These include individual employee files that are created, received, and maintained by the DLA Disability Program Manager, DLA Field Activity Disability Program Coordinators or employee relations coordinators, immediate supervisors, Computer/Electronic Accommodation Program (CAP) administrator, or Human Resource specialists containing records of requests by or for an employee or applicant for employment for reasonable accommodation and/or assistive technology devices and services through the agency or CAP. This series also includes, but is not limited to, request approvals and denials, notice of procedures for informal dispute resolution or appeal processes, forms, correspondence, emails, records of oral conversations, medical documentation, and notes.

Supplemental files are destroyed three years after end of fiscal year in which accommodation is decided or when all appeals are concluded, whichever is later. Supplemental files may include records created, received, and maintained by the DLA Disability Program Manager, DLA Field Activity Disability Program Coordinators or employee relations coordinators, while advising on, implementing or appealing requests for or from an individual employee or applicant for employment for reasonable accommodation. Some requests may involve Human Resource matters, including but not limited to changes in duties, reassignments, leave usage, and performance issues. Files may include, but are not limited to, policy guidance, resource information about accommodation providers, forms, emails, notes.

Tracking system records and data created, received, and maintained for purposes of tracking agency compliance with Executive Order 13164 and U.S. Equal Employment Opportunity Commission (EEOC) guidance are deleted/destroyed three years after compliance report is filed or when no longer needed for reference.

SYSTEMS MANAGER(S) AND ADDRESS:

Director, Equal Employment Opportunity, Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6221.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221 or to the Privacy Act Office of the DLA Field Activity where Reasonable Accommodation was requested. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

Written inquiry should contain the individual's full name and the date of the request for accommodation.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Privacy Act Office, Headquarters, Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221 or to the Privacy Act Office of the DLA Field Activity where Reasonable Accommodation was requested. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

Written inquiry should contain the individual's full name and the date of the request for accommodation.

CONTESTING RECORD PROCEDURES:

The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Office, Headquarters, Defense Logistics Agency, *ATTN:* DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

RECORD SOURCE CATEGORIES:

Individual requesting Reasonable Accommodation, input from individual's supervisor/manager, documentation from individual's medical practitioner, and/or agency medical representative.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26776 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE, Formerly Known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Fiscal Year (FY) 2009 Mental Health Rate Updates

AGENCY: Department of Defense.

ACTION: Notice of updated mental health rates for FY 2009.

SUMMARY: This notice provides the updated regional per diem rates for low volume mental health providers; the update factor for hospital-specific per diems; the updated cap per diem for high-volume providers; the beneficiary per diem cost share amount for low-volume providers; and, the updated per diem rates for both full-day and half-day TRICARE Partial Hospitalization Programs for FY 2009.

DATES: *Effective Date:* The FY 2009 rates contained in this notice are effective for services on or after October 1, 2008.

FOR FURTHER INFORMATION CONTACT: Ann N. Fazzini, Medical Benefits and Reimbursement Branch, TRICARE Management Activity, telephone (303) 676–3803.

SUPPLEMENTARY INFORMATION: The final rule published in the **Federal Register** on September 6, 1988, (53 FR 34285) set forth reimbursement changes that were effective for all inpatient hospital admissions in psychiatric hospitals and exempt psychiatric units occurring on or after January 1, 1989. The final rule published in the **Federal Register** on July 1, 1993 (58 FR 35–400), set forth maximum per diem rates for all partial hospitalization admissions on or after September 29, 1993. Included in these final rules were provisions for updating reimbursement rates for each federal fiscal year. As stated in the final rules,

each per diem shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare Prospective Payment System (i.e., the update factor for inpatient psychiatric facilities). For FY 2009, Medicare has recommended a rate of increase of 3.2 percent. TRICARE will adopt this update factor for FY 2009 as the final update factor. Hospitals and units with hospital specific rates (hospitals and units with high TRICARE volume) and regional specific rates for psychiatric hospitals and units with low TRICARE volume will have their TRICARE rates for FY 2008 updated by 3.2 percent for FY 2009. Partial hospitalization rates for full-day and half-day programs will also be updated by 3.2 percent for FY 2009. The cap amount for high-volume hospitals and units will also be updated by the 3.2 percent for FY 2009. The beneficiary cost share for low volume hospitals and units will also be updated by 3.2 percent for FY 2009.

Per Title 32, Code of Federal Regulations (CFR), Part 199.14, the same area wage indexes used for the CHAMPUS DRG-based payment system shall be applied to the wage portion of the applicable regional per diem for each day of the admission. The wage portion shall be the same as that used for the CHAMPUS DRG-based payment system. For wage index values greater than 1.0, the wage portion of the regional rate subject to the area wage adjustment is 69.7 percent for FY 2009. For wage index values less than or equal to 1.0, the wage portion of the regional rate subject to the area wage adjustment is 62 percent. Additionally, Title 32, CFR Part 199.14, requires that hospital specific and regional per diems shall be updated by the Medicare update factor for hospitals and units exempt from the Medicare prospective payment system.

The following reflect an update of 3.2 percent for FY 2009.

REGIONAL SPECIFIC RATES FOR PSYCHIATRIC HOSPITALS AND UNITS WITH LOW TRICARE VOLUME FOR FISCAL YEAR 2009

United States Census Region	Regional rate
Northeast:	
New England	$730
Mid-Atlantic	703
Midwest:	
East North Central	607
West North Central	573
South:	
South Atlantic	723
East South Central	774
West South Central	659
West:	
Mountain	658
Pacific	778
Puerto Rico	496

Beneficiary cost share: Beneficiary cost-share (other than dependents of Active Duty members) for care paid on the basis of a regional per diem rate is the lower of $193 per day or 25 percent of the hospital billed charges effective for services rendered on or after October 1, 2008.

Cap Amount: Updated cap amount for hospitals and units with high TRICARE volume is $917 per day for FY 2009.

The following reflect an update of 3.2 percent for FY 2009.

PARTIAL HOSPITALIZATION RATES FOR FULL-DAY AND HALF-DAY PROGRAMS

[Fiscal year 2009]

United States Census Region	Full-day rate (6 hours or more)	Half-day rate (3–5 hours)
Northeast:		
New England (Maine, N.H., Vt., Mass., R.I., Conn.)	$293	$221
Mid-Atlantic:		
(N.Y., N.J., Penn.)	318	239
Midwest:		
East North Central (Ohio, Ind., Ill., Mich., Wis.)	280	209
West North Central:		
(Minn., Iowa, Mo., N.D., S.D., Neb., Kan.)	280	209
South:		
South Atlantic (Del., Md., D.C., Va., W.Va., N.C., S.C., Ga., Fla.)	301	226
East South Central:		
(Ky., Tenn., Al., Miss.)	325	245
West South Central:		
(Ark., La., Texas, Okla.)	325	245
West:		
Mountain (Mon., Idaho, Wyo., Col., N.M., Ariz., Utah, Nev.)	328	248
Pacific (Wash., Ore., Calif., Alaska, Hawaii)	322	241
Puerto Rico	209	158

The above rates are effective for services rendered on or after October 1, 2008.

Dated: November 4, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–26759 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2008–0033]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to delete a system of records.

SUMMARY: The Department of the Air Force is deleting a system of records in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008, unless comments

are received which result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCISI, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The Department of Air Force proposes to delete a system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F024 AF DP A

SYSTEM NAME:

Application for Early Return of Dependents (June 11, 1997, 62 FR 31793).

REASON:

The records collected in this system notice have been incorporated into System of Record Notice (SORN) F036 AF PC C, Family Services Volunteer and Request for Early Return Records (June 11, 1997, 62 FR 31793). Because these records are accurately referenced in another system notice, system notice F024 AF DP A is duplicative and should be deleted.

[FR Doc. E8–26748 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2008–0031]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to alter a system of records notice.

SUMMARY: The Department of the Air Force proposes to alter a system of records notice to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The actions will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 522a(r) of the Privacy Act of 1974, as amended, was submitted on October 24, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F031 11 SPS A

SYSTEM NAME:

Presidential Support Files (June 11, 1997, 62 FR 31793).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Presidential Advance Agent Scheduling System Records.''

SYSTEM LOCATION:

Delete entry and replace with ''Headquarters, United States Air Force Presidential Flight Support, 1670 Air Force Pentagon, Room 4C887, Washington DC 20330–1670.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Active duty Air Force personnel, Air Force Reserve and Air National Guard military personnel.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Individual's name, date of birth, work/home/cell phone numbers, work/home addresses, Social Security Number (SSN), passport number and dates, security clearance status, training requirement status, and Spouse's name.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 8032, the Air Staff: general duties; and EO 9397 (SSN).''

PURPOSE(S):

Delete entry and replace with ''The system contains records used to schedule and execute worldwide travel for Air Force Presidential Advance Agents.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Department of the Air Force, 1777 N Kent St (RPN), Suite 3200, Rosslyn, VA 22209–2110.''

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Information is received from the individual and personnel records.''

* * * * *

F031 11 AF SPS A

SYSTEM NAME:

Presidential Advance Agent Scheduling System Records.

SYSTEM LOCATION:

Headquarters, United States Air Force Presidential Flight Support, 1670 Air Force Pentagon, Room 4C887, Washington D.C. 20330–1670.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty Air Force personnel, Air Force Reserve and Air National Guard military personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, date of birth, work/home/cell phone numbers, work/home addresses, Social Security Number (SSN), passport number/dates, security clearance status, training requirement status, and Spouse's name.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 8032, the Air Staff: general duties; and EO 9397 (SSN).

PURPOSE(S):

The system contains records used to schedule and execute worldwide travel

for Air Force Presidential Advance Agents.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The DoD Blanket Routine Uses published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are in file folders and electronic storage media.

RETRIEVABILITY:

Files are retrieved by individual's name.

SAFEGUARDS:

Records are accessed by persons responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need to know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software.

RETENTION AND DISPOSAL:

Retain records until they are obsolete. Records are destroyed by burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Department of the Air Force, 1777 N Kent St (RPN), Suite 3200, Rosslyn, VA 22209–2110.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether data about themselves are contained in this system should address written inquiries to Department of Air Force, 1670 Air Force Pentagon, Washington DC 20330–1670.

Requests should contain individual's name and dates they were an Advance Agent.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about them is contained in this system should address written inquiries to Department of Air Force, 1670 Air Force Pentagon, Washington DC 20330–1670.

Requests should contain individual's name and dates they were an Advance Agent

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is received from the individual and personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26750 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2008–0027]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to alter a system of records notice.

SUMMARY: The Department of the Air Force proposes to alter a system of records notice to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 522a(r) of the Privacy Act of 1974, as amended, was submitted on October 24, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F051 AF JA H

SYSTEM NAME:

Claims Records (June 11, 1997, 62 FR 31793).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420. Headquarters of major commands and at all levels down to and including Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.''

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''All records necessary to adjudicate a claim, to include reports from other DoD offices; federal and state agencies; foreign governments; and witness statements.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 8013, Secretary of the Air Force; U.S.C. 8037, Judge Advocate General, Deputy Judge Advocate General: Appointment and duties; Air Force Instruction 51–501, Tort Claims; Air Force Instruction 51–502, Personnel and Government Recovery Claims and E.O. 9397 (SSN).''

PURPOSE(S):

Delete entry and replace with ''Records are used for claims adjudication and processing, budgeting, and management of claims. Records are also used as necessary in civil litigation involving the United States.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

After the second paragraph, add to entry ''To any other federal agency for the purpose of adjudicating claims and civil litigation.

To state and local entity for the purpose of claims processing and civil litigation involving the Air Force.

To any person or entity for the purpose of completing the Air Force's structured settlements.

To foreign governments and courts, carriers and their insurance companies for all purposes involving the

investigation and payment of claims filed against the Air Force or in which the Air Force is an interested party.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper records in file folders and on electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Retrieved by name, Social Security Number (SSN); and/or claim number.''

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with ''Retained in office either one or two years depending upon type of claim, then destroyed after four additional years at staging area; after agency action completed others are held one, three, five years or ten years, depending on the type of claim and type of record. Paper files are disposed of by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by deleting, erasing, degaussing, or by overwriting.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330, or to the Staff Judge Advocate at the concerned subordinate command or installation.

Requests should include full name and proof of identity, date of incident and claim number, date and type of claim, location of incident may also be required.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330; or to the Staff Judge Advocate at the concerned subordinate command or installation.

Requests should include full name and proof of identity, date of incident and claim number, date and type of claim, location of incident may also be required.''

* * * * *

F051 AF JA H

SYSTEM NAME:

Claims Records.

SYSTEM LOCATION:

The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420. Headquarters of major commands and at all levels down to and including Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals filing administrative claims against the Air Force or against whom the Air Force has filed an administrative claim.

CATEGORIES OF RECORDS IN THE SYSTEM:

All records necessary to adjudicate a claim, to include reports from other DoD offices; federal and state agencies; foreign governments; and witness statements.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; U.S.C. 8037, Judge Advocate General, Deputy Judge Advocate General: Appointment and duties; Air Force Instruction 51–501, Tort Claims; Air Force Instruction 51–502, Personnel and Government Recovery Claims and E.O. 9397 (SSN).

PURPOSE(S):

Records are used for claims adjudication and processing, budgeting, and management of claims. Records are also used as necessary in civil litigation involving the United States.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows: To any other federal agency for the purpose of adjudicating claims and civil litigation.

To state and local entity for the purpose of claims processing and civil litigation involving the Air Force.

To any person or entity for the purpose of completing the Air Force's structured settlements.

To foreign governments and courts, carriers and their insurance companies for all purposes involving the investigation and payment of claims filed against the Air Force or in which the Air Force is an interested party.

The ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and on electronic storage media.

RETRIEVABILITY:

Retrieved by name, Social Security Number (SSN) and/or claim number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software. Computers must be accessed with a password.

RETENTION AND DISPOSAL:

Retained in office either one or two years depending upon type of claim, then destroyed after four additional years at staging area; after agency action completed others are held one, three, five years or ten years, depending on the type of claim and type of record. Paper files are disposed of by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by deleting, erasing, degaussing, or by overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330, or to the Staff Judge Advocate at the concerned subordinate command or installation.

Requests should include full name and proof of identity, date of incident and claim number, date and type of

claim, location of incident may also be required.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330; or to the Staff Judge Advocate at the concerned subordinate command or installation.

Requests should include full name and proof of identity, date of incident and claim number, date and type of claim, location of incident may also be required.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from federal agency reports, claimants, medical institutions, police and investigating officers, the public media, bureaus of motor vehicles, state or local governments, and witnesses.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26752 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2008–0032]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Department of the Air Force proposes to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F011 ACC B

SYSTEM NAME:

Airborne Warning and Control System (AWACS) Records.

SYSTEM LOCATION:

Department of Air Force, 552d Air Control Wing, Tinker AFB, 552d Air Control Group (552 ACG), 7575 Sentry Blvd, Suite 117, Tinker AFB, OK 73145–9037.

Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty military personnel, Air Force civilian employees, Air Force contractors, Air Force Reserve and those foreign military personnel who are attached to the U.S. Air Force (USAF) for flying support.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel records related to an individual's ancillary training, qualifications, and schedules. Data fields contained in the records include: full name, e-mail address, Social Security Number (SSN), work phone, location, organization, job series, and grade.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 8013, Secretary of the Air Force; AFI 11–202V2 ACC Sup Aircrew Standardization/Evaluation Program; AFI 11–401 Aviation Management; ACCI 11–464 Training Records and Performance Evaluation in Formal Flying Training Programs; and EO 9397 (SSN).

PURPOSE(S):

To manage and administer Air Force aviation and non-flying operations. This includes aircrew training and evaluation, flight schedule functions, flying safety and related functions needed to attain and maintain combat or mission readiness, ancillary training, scheduling functions, mobility/deployment requirements tracking.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Individual's name and/or Social Security Number (SSN).

SAFEGUARDS:

AMS provides detailed and specific access levels and permissions to ensure that only authorized users have access to read and or write information, or perform other operations with the system. Access will be granted using the Common Access Card (CAC) or username/password security model. A combination of physical, personnel, and system-enforced security mechanisms control access. All accesses, whether procedural or system-enforced, are adjudicated based on each person's authorized ''need-to-know.''

RETENTION AND DISPOSAL:

Maintained until superseded, obsolete, or no longer needed. Destroy paper records by tearing, pulping, burning, shredding, or macerating. Destroy computer records by overwriting or degaussing.

SYSTEM MANAGER AND ADDRESS:

Chief, Maintenance Data Systems Analysis Section, Department of Air Force, 552d Air Control Group (552 ACG), ATTN: AMS PGM, 7575 Sentry Blvd, Suite 117, Tinker AFB, OK 73127–9037.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to Department of Air Force, 552d Air Control Group (552 ACG), ATTN: AMS PGM, 7575 Sentry Blvd, Suite 117, Tinker AFB, OK 73127–9037.

Individuals may also contact the system manager at each unit utilizing AMS or the Host Database Manager. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

In order to obtain records that are in AMS's files, a requester must submit a written request to 552d Air Control Group (552 ACG). Individuals wishing to file a request with 552 ACG must address their request in writing to 552d Air Control Group (552 ACG), Attn: AMS Program Manager, 7575 Sentry Blvd, Ste 117, Tinker AFB, OK 73145–2713.

Written requests must contain specific information about each record sought, such as the date, title or name, author, recipient and subject matter of the record.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to 552d Air Control Group (552 ACG), ATTN: AMS PGM, 7575 Sentry Blvd, Suite 117, Tinker AFB, OK 73127–9037.

Individuals may also contact the system manager at each unit utilizing AMS or the Host Database Manager. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

In order to obtain records that are in AMS's files, a requester must submit a written request to 552d Air Control Group (552 ACG). Individuals wishing to file a request with 552 ACG must address their request in writing to 552d Air Control Group (552 ACG), Attn: AMS Program Manager, 7575 Sentry Blvd, Ste 117, Tinker AFB, OK 73145–2713.

Written requests must contain specific information about each record sought, such as the date, title or name, author, recipient and subject matter of the record.

CONTESTING RECORDS PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Automated system interfaces and source documents. AMS has an interface with the Air Force Resource Management System (AFORMS).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26753 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2008–0030]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Air Force proposes to alter a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F036 SAFCB A

SYSTEM NAME:

Military Records Processed by the Air Force Correction Board (May 7, 1999, 64 FR 24605).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Air Force Correction Board Records.''

SYSTEM LOCATION:

Delete entry and replace with ''Office of the Secretary of the Air Force, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002 and the Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409–8001.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''All members or former members of the Air Force; Army Air Forces, Air Corps, United States Army; Air Service, United States Navy; and Aviation Section, Signal Corps, United States Army, who have applied to the Air Force Board for the Correction of Military Records (AFBCMR), Physical Disability Board of Review (PDBR), Secretary of the Air Force Personnel Council (SAFPC), or Air Force Civilians applying to the Air Force Civilian Appellate Review Office (AFCARO).''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Individual's name, Social Security Number (SSN), case number, applications for correction of military records, applications to the PDBR, Secretary of the Air Force Personnel Council (SAFPC) or civilian complaints processed by the Department of the Air Force AFCARO with supporting evidence, staff advisory opinions and final determinations.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 1554a, DoD Disability Review Board and E.O. 9397 (SSN).''

PURPOSE(S):

Delete entry and replace with ''To review applications for correction of military records to determine the existence of an error or injustice, to review disability ratings for medical separations and, when appropriate,

make recommendations to the Secretary of the Air Force and other Service Secretaries.

Additionally, to review and make determinations of cases boarded by the SAFPC and complaints processed by AFCARO.''

* * * * *

STORAGE:

Delete entry and replace with ''Maintained in file folders and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''By name and Case Number.''

SAFEGUARDS:

Delete entry and replace with ''Paper and electronic records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Electronic records are additionally password protected. A record of access by identity is recorded and retrievable.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Executive Secretary, Air Force Review Boards Agency, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individual seeking to determine whether this system of records contains information on themselves should address inquiries to the Executive Secretary, Air Force Board for the Correction of Military Records, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.

Request must provide applicant's full name, Social Security Number (SSN), and docket number (if known/applicable).''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking to access records about themselves contained in this system should address requests to the Executive Secretary, Air Force Review Boards Agency, Headquarters, United States Air Force, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.

Request must provide applicant's full name, Social Security Number (SSN), and docket number (if known/applicable).''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The Air Force rules for accessing records and for contesting and appealing initial agency determinations are published in Air Force Instruction 33–332, Privacy Act Program; 32 CFR part 806b; or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Information is obtained from applicants, forms, Air Force offices and/or other Government agencies.''

* * * * *

F036 SAFCB A

SYSTEM NAME:

Air Force Correction Board Records.

SYSTEM LOCATION:

Office of the Secretary of the Air Force, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002 and the Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409–8001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All members or former members of the Air Force; Army Air Forces, Air Corps, United States Army; Air Service, United States Navy; and Aviation Section, Signal Corps, United States Army, who have applied to the Air Force Board for the Correction of Military Records (AFBCMR), Physical Disability Board of Review (PDBR), Secretary of the Air Force Personnel Council (SAFPC), or Air Force Civilians applying to the Air Force Civilian Appellate Review Office (AFCARO).

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number (SSN), case number, applications for correction of military records, applications to the PDBR, Secretary of the Air Force Personnel Council (SAFPC) or civilian complaints processed by the Department of the Air Force AFCARO with supporting evidence, staff advisory opinions and final determinations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 1554a, DoD Disability Review Board and E.O. 9397 (SSN).

PURPOSE(S):

To review applications for correction of military records to determine the existence of an error or injustice, to review disability ratings for medical separations and, when appropriate, make recommendations to the Secretary of the Air Force and other Service Secretaries. Additionally, to review and make determinations of cases boarded by the SAFPC and complaints processed by AFCARO.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders and electronic storage media.

RETRIEVABILITY:

By name and Case Number.

SAFEGUARDS:

Paper and electronic records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Electronic records are additionally password protected. A record of access by identity is recorded and retrievable.

RETENTION AND DISPOSAL:

Case files are maintained for 75 years then destroyed. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Executive Secretary, Air Force Review Boards Agency, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.

NOTIFICATION PROCEDURE:

Individual seeking to determine whether this system of records contains information on themselves should address inquiries to the Executive Secretary, Air Force Board for the Correction of Military Records, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.

Request must provide applicant's full name, Social Security Number (SSN), and docket number (if known/applicable).

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address requests to the Executive Secretary, Air Force Review Boards Agency, Headquarters, United States Air Force, 1535 Command Drive, Andrews Air Force Base, MD 20762–7002.

Request must provide applicant's full name, Social Security Number (SSN), and docket number (if known/applicable).

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting and appealing initial agency determinations are published in Air Force Instruction 33–332, Privacy Act Program; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is obtained from applicants, forms, Air Force offices and/or other Government agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26755 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2208–0025]

Privacy Act of 1974; System of Records

AGENCY: Department of Air Force, DoD.

ACTION: Notice to delete a system of records.

SUMMARY: The Department of Air Force proposes to delete a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCISI, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The Department of the Air Force proposes to delete a system of records from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F031 AFMC A

SYSTEM NAME:

AFMC Badge and Vehicle Control Records (June 11, 1997, 62 FR 31793).

REASON:

This records collection for this system is already covered by F031 AF SF B, Security Forces Management Information System (SFMIS) published on October 14, 2003, 68 FR 59168. Accordingly, this Privacy Act System of Records Notice will be deleted from the Air Force's inventory.

[FR Doc. E8–26756 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2008–0026]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Department of the Air Force is proposing to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCISI, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on October 21, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

FO24 AF USTRANSCOM D DoD

SYSTEM NAME:

Defense Transportation System Records.

SYSTEM LOCATION:

Installation Transportation Offices, Joint Personal Property Shipping Offices, Aerial and Surface Ports of Embarkation, world-wide. Addresses may be obtained from the Commander, Headquarters, Military Surface Deployment and Distribution Command, 709 Ward Drive, Building 1990, Scott Air Force Base IL 62225–5004.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD personnel (military and civilian) and dependents (as applicable) with official authorization.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, rank, unit identification code (UIC), Service affiliation, personal identifiers (*i.e.* Social Security Number (SSN), home address, home telephone, emergency contact information) and other information relating to personnel and movement of personal property.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 100–562, Imported Vehicle Safety Compliance Act of 1988; 5 U.S.C. 5726, Storage Expenses, Household Goods and Personal Effects; 10 U.S.C. 113, Secretary of Defense; 10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 8013, Secretary of the Air Force, 19 U.S.C. 1498, Entry Under Regulations; 37 U.S.C. 406, Travel and

Transportation Allowances, Dependents, Baggage and Household Effects; Federal Acquisition Regulation (FAR); Joint Federal Travel Regulation (JTR), Volumes I and II, DoD Directive 4500.9E, Transportation and Traffic Management; DOD Directive 5158.4, United States Transportation Command; DoD Instruction 4500.42, DoD Transportation Reservation and Ticketing Services; DoD Regulation 4140.1, DoD Materiel Management Regulation; DoD Regulation 4500.9, Defense Transportation Regulation; and DoD Regulation 4515.13–R, Air Transportation Eligibility and E.O. 9397 (SSN).

PURPOSES:

To schedule the movement of DoD personnel (military and civilian) and dependents traveling in the Defense Transportation System; schedule the movement, storage, and handling of personal property; to identify and trace lost shipments; to submit claims for damaged or loss shipments; U.S. customs protection of personal property; payment of commercial transportation providers under contract and tenders to the DoD; monitor effectiveness of personal property traffic management functions.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. a(b)(3) as follows:

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To disclose to private sector commercial transportation service providers, who are under contract with the DoD for shipment/storage of personal property, to identify ownership, schedule pick up and delivery of personal property, to include privately owned vehicles, motorcycles, and house trailers/motor homes, Bill of Lading for services rendered, personal property counseling checklist.

To U.S. Customs and Border Protection Declaration for personal property shipments, re-weigh of personal property, shipment evaluation and inspection reports, receipt for unaccompanied baggage, mobile home inspection record, temporary commercial storage at Government expense, accessorial services-mobile home, report of contractor services, and claims for loss and damage.

To manifest DoD personnel and dependents (as applicable) traveling in the Defense Transportation System with official DoD authorization.

To provide emergency contact information to the designated authorized carrier under DoD contract and DoD authorizing activity, in the event of an emergency.

To disclose information to a Federal agency in order to manage and optimize DoD transportation resources.

To the Department of State to locate DoD personnel and dependents (as applicable) with official DoD authorization moving within the Defense moving within the Defense Transportation System within foreign countries.

To disclose information to a Federal agency for accumulating reporting data and monitoring of the system.

To General Service Administration and Defense Government Accounting Activities for processing government Bill of Lading.

The Department of Defense ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Individual's Surname and Social Security Number (SSN).

SAFEGUARDS:

Records are maintained in a secured environment accessible to authorized personnel having an official need-to-know. Automated segments are further protected by secure log-in, passwords, and Common Access Card.

RETENTION AND DISPOSAL:

Documents are destroyed after 6 years.

SYSTEM MANAGER AND ADDRESS:

Commander, United States Transportation Command, Attn: TCJ5/4, 508 Scott Drive, Scott AFB, IL 62225–5357.

NOTIFICATION PROCEDURE:

Individuals seeking access to information about themselves contained in this system should address written inquiries to Air Force Privacy Act Officer, Officer of Warfighting Integration and Chief Information Officer, SAF/XCISI, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

Requests should contain full name, social security number (SSN), current address and telephone number, and any information which will assist in locating the records requested (e.g. type of shipment, origin, destination, date of application).

CONTESTING RECORD PROCEDURES:

The Department of the Air Force's rules for assessing records, for contesting contents an appealing initial agency determinations are published in AFI 33–332, 32 CFR part 806b, or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual completing application for entry into the Defense Transportation System and from the private sector transportation service provider.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26765 Filed 11–10–08; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2008–0034]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to add a system of records notice.

SUMMARY: The Department of the Air Force proposes to add a system of records notice to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Ken Brodie at (703) 696–6518.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's record system notices for records systems subject to the Privacy Act of1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 522a(r) of the Privacy Act of 1974, as amended, was submitted on October 30, 2008 to the

House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F036 AETC Y

SYSTEM NAME:

Training Integration Management System (TIMS) Records.

SYSTEM LOCATION:

Department of Air Force, 12th Operational Support Squadron, Bldg. 740, Suite 1, 501 I Street East, Randolph Air Force Base, TX 78150–4336.

Department of Air Force, 12th Operational Support Squadron, Bldg. 990, Room 105, 151 J Street East, Randolph Air Force Base, TX 78150–4336.

Department of Air Force, 14th Operational Support Squadron, Bldg. 230, Room 25, 144 Liberty Street, Columbus Air Force Base, MS 39701–4001.

Department of Air Force, 47th Operations Group, Bldg. 320, Room 1183, 417 Liberty Drive, Laughlin Air Force Base, TX 78843–5133.

Department of Air Force, 80th Operational Support Squadron, Bldg. 2320, Room C–141, 835 20th Avenue, Sheppard Air Force Base, TX 76311–2030.

Department of Air Force, 71st Operational Support Squadron, Bldg. 672, Room 145, 173 Merritt Road, Vance Air Force Base, OK 73705–5214.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All students and cadre involved in the flight training operations to include active duty U.S. Air Force and U.S. Navy personnel; Air National Guard and reserve personnel, Department of Defense (DoD) civilians and contractors, and foreign national military.

CATEGORIES OF RECORDS IN THE SYSTEM:

Biographical and background information including name, grade, and Social Security Number (SSN), source of commission, education including university, dates of attendance, graduation degree(s), major and date; past training unit of assignment; class number, section number, flying and academic courses completed; complete record of evaluations including grades on each phase of flight evaluations and overall flight evaluation performance in each category of training, flying hours; date graduated or eliminated to include with reasons for elimination and Training Review Board proceedings and records which document aircrew training, evaluations, performance, and accomplishments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; Air Education and Training Command Instructions; AETCI 36–2205 Formal Aircrew Training Administration and Management; AETCI 36–2220, Academic Training; AETCI 36–2223, Flying Training Student Information Management; and Executive Order 9397(SSN).

PURPOSE(S):

To manage all aspects of Joint Air Force and Navy primary aircraft student training. Provides scheduling of all resources-students, instructors, classrooms, classroom equipment and resource files, aircrew training (simulator) devices, aircraft, and airspace. I will maintain data and provide performance evaluation and deficiency tracking of students. In addition, it will manage syllabi and evaluates training course content. The system also monitors student performance by source of entry, education level, and minority status, maintains background information and qualifications of graduates for follow-on training to Air National Guard, Air Force and Navy Reserve, and other Air Force and Navy training units. Provides data for and documents proceedings in the event of Training Review Board actions. Maintains data and tracks the training, and qualifications of instructor pilots and other training cadre.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of record system notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Individual's name and Social Security Number (SSN).

SAFEGUARDS:

Computer databases are located in locked servers in locked rooms in flying training classroom/laboratory buildings on Air Force and Navy installations. Backup tapes are stored in locked theft-proof and fireproof cabinets in locked rooms. All training facilities with system-accessible workstations are controlled during duty hours and secured after duty hours. Access to record, (database) data, by users (including students, training cadre, flight training managers, and system administrators) are controlled by Common Access Card (CAC) identification. Authorized access to specific data is controlled in accordance with user roles and permissions. User roles and permissions are established and assigned in accordance with individual responsibilities; i.e., student, instructor, training manager, system manager.

RETENTION AND DISPOSAL:

Retained as active at least two years. Hardcopy records are destroyed by tearing into pieces, shredding, pulping, macerating or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff Operations, Headquarters Air Education and Training Command, 1 F Street, Suite 2, Randolph Air Force Base, TX 78150–4322.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Deputy Chief of Staff Operations, Headquarters Air Education and Training Command, 1 F Street, Suite 2, Randolph Air Force Base, TX 78150–4322.

Individuals should provide their full name, Social Security Number (SSN), office or organization where currently assigned, if applicable, current address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Deputy Chief of Staff Operations, Headquarters Air

Education and Training Command, 1 F Street, Suite 2, Randolph Air Force Base, TX 78150–4322.

Individuals should provide their full name, Social Security Number (SSN), office or organization where currently assigned, if applicable, current address, and telephone number.

CONTESTING RECORDS PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual and other DoD systems.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26767 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2008–0029]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Air Force proposes to alter a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F051 AFJA D

SYSTEM NAME:

Patent Infringement and Litigation Records (March 14, 2002, 67 FR 11467).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Department of the Air Force, 1501 Wilson Blvd, AFLOA/JACQ, Suite 606, Arlington, VA 22209–2103. Department of the Air Force, 2240 B Street, AFMC LO/JAZ, Room 100, Wright-Patterson Air Force Base, OH 45433–7902.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Individuals who have alleged unlicensed use of their patents, trademarks, or copyrights by the Air Force, or who have brought suit against the United States concerning patent, trademark, copyright, or other intellectual property matters.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''All documents necessary to adjudicate allegations made by individuals, to include but not limited to: individual's name, letters and memoranda; messages; forms; reports; contracts; bids; photographs; legal opinions; pleadings; infringement studies; validity studies; procurement information; license agreements; contract determinations, witness statements, and engineering and technical reports.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 8037, Judge Advocate General, Deputy Judge Advocate General: Appointment and duties; 10 U.S.C. 2386, Copyrights, patents, designs; 15 U.S.C. 1122, Liability of the United States for trademark infringement; 22 U.S.C. 2356, Foreign Assistance, acquisition; 28 U.S.C. 1491, Claims against the United States; 28 U.S.C. 1498, Patent and copyright cases; 35 U.S.C. 183, Right to compensation for secrecy order matters; [and] Department of Defense FAR Supplement Subpart 227.70, Infringement claims, licenses, and assignments and E.O. 9397(SSN).''

PURPOSE(S):

Delete entry and replace with ''To enable the United States and its officers and employees to investigate claims and/or defend the legal interests of the United States because of claims for compensation and litigation involving patent, trademark copyright, and other intellectual property matters.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

After the first paragraph, delete entry and replace with ''To the U.S. Patent and Trademark Office to the extent such disclosures are necessary for the processing and verification of patent applications.

To the Department of Justice for the purpose of asserting and defending patent infringement action.

The DoD 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper records in file folders and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Retrieved by name''.

SAFEGUARDS:

Delete entry and replace with ''Records are accessed by authorized personnel as necessary to accomplish their official duties. Paper records are stored in locked containers and/or secured facilities. Computer records have access controls, to include password protection and encryption.''

RETENTION AND DISPOSAL:

Delete and replace with ''Retained in office files for up to three years after the case is closed, then retired to the Washington National Records Center, Washington, DC 20409, for retention up to twenty years. Paper records are destroyed by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by deleting, erasing, degaussing, or by overwriting.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force

Pentagon, Washington, DC 20330–1420, or designee.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to The Judge Advocate General, Headquarters, United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.

Requests should include name and proof of identity, such as driver's license or other government issued ID card.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves in this system should address written inquiries to The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.

Requests should include name and proof of identity, such as driver's license or other government issued ID card.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Information received from individuals, government agencies, court documents, corporations (non-contractors) and from source documents.''

* * * * *

F051 AFJA D

SYSTEM NAME:

Patent Infringement and Litigation Records.

SYSTEM LOCATION:

Department of the Air Force, 1501 Wilson Blvd, AFLOA/JACQ, Suite 606, Arlington, VA 22209–2103.

Department of the Air Force, 2240 B Street, AFMC LO/JAZ, Room 100, Wright-Patterson Air Force Base, OH 45433–7902.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have alleged unlicensed use of their patents, trademarks, or copyrights by the Air Force, or who have brought suit against the United States concerning patent, trademark, copyright, or other intellectual property matters.

CATEGORIES OF RECORDS IN THE SYSTEM:

All documents necessary to adjudicate allegations made by individuals, to include but not limited to: individual's name, letters and memoranda; messages; forms; reports; contracts; bids; photographs; legal opinions; pleadings; infringement studies; validity studies; procurement information; license agreements; contract determinations, witness statements, and engineering and technical reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 8037, Judge Advocate General, Deputy Judge Advocate General: Appointment and duties; 10 U.S.C. 2386, Copyrights, patents, designs; 15 U.S.C. 1122, Liability of the United States for trademark infringement; 22 U.S.C. 2356, Foreign Assistance, acquisition; 28 U.S.C. 1491, Claims against the United States; 28 U.S.C. 1498, Patent and copyright cases; 35 U.S.C. 183, Right to compensation for secrecy order matters; [and] Department of Defense FAR Supplement Subpart 227.70, Infringement claims, licenses, and assignments and E.O. 9397 (SSN).

PURPOSE(S):

To enable the United States and its officers and employees to investigate claims and/or defend the legal interests of the United States because of claims for compensation and litigation involving patent, trademark copyright, and other intellectual property matters.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the U.S. Patent and Trademark Office to the extent such disclosures are necessary for the processing and verification of patent applications.

To the Department of Justice for the purpose of asserting and defending patent infringement action.

The DoD 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by authorized personnel as necessary to accomplish their official duties. Paper records are stored in locked containers and/or secured facilities. Computer records have access controls, to include password protection and encryption.

RETENTION AND DISPOSAL:

Retained in office files for up to three years after the case is closed, then retired to the Washington National Records Center, Washington, DC 20409, for retention up to twenty years. Paper records are destroyed by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by deleting, erasing, degaussing, or by overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420, or designee.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to The Judge Advocate General, Headquarters, United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.

Requests should include name and proof of identity, such as driver's license or other government issued ID card.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves in this system should address written inquiries to The Judge Advocate General, Headquarters United States Air Force, 1420 Air Force Pentagon, Washington, DC 20330–1420.

Requests should include name and proof of identity, such as driver's license or other government issued ID card.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information received from individuals, government agencies, court documents, corporations (non-contractors) and from source documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26774 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2008–0028]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to Add a New System of Records.

SUMMARY: The Department of the Air Force proposes to add a new system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on December 12, 2008, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of Warfighting Integration and Chief Information Officer, SAF/XCX, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Brodie at (703) 696–7557.

SUPPLEMENTARY INFORMATION: The Department of the Air Force's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

AETC F036 AETC Z

SYSTEM NAME:

Basic Training Management System (BTMS) Records.

SYSTEM LOCATION:

Training Delivery & Administration, 737th Training Support Squadron (737 TRSS/TSDT), 737 Training Group, Bldg 6420,1618 Truemper Street, Lackland AFB, TX 78236–5511.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

U.S. Air Force enlisted trainees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual student records containing individual's name, Social Security Number (SSN), written test results, physical fitness results, counseling records, training progress check results, emergency notification data, height/weight information, training waivers, discharge case disposition (if applicable), and other documents pertaining to student accountability and administration.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; as implemented by Air Force Instruction 36–2608, Air Education and Training Command Instruction (AETCI) 36–2203, Training Administration and E.O. 9397 (SSN).

PURPOSE:

Used to evaluate and record performance/progress of student, and to determine generate statistics to measure the health and effectiveness of Basic Military Training (BMT).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3).

The DoD ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic Storage Media.

RETRIEVABILITY:

By name and Social Security Number (SSN).

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties, and by authorized personnel who are properly screened and cleared for need-to-know. All access is based upon role-based logons. User's level of access is restricted by their role within the organization.

RETENTION AND DISPOSAL:

Computer data is actively maintained only for the period the trainee is enrolled in basic military training. Upon graduation, data is retained for 18 months and destroyed by deleting files, erasing, degaussing or overwriting using approved Air Force procedures and products.

SYSTEM MANAGER AND ADDRESS:

Department of the Air Force, Chief, Training Delivery & Administration, 737th Training Support Squadron (737 TRSS/TSDT), 1618 Truemper Street, Lackland AFB TX 78236–5511.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to or visit the 737th Training Group, 1618 Truemper Street, Lackland AFB TX 78236–5511 or via e-mail at *737TRG.CCE@Lackland.af.mil.*

Request must contain name and Social Security Number (SSN).

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to or visit the 737th Training Group, 1618 Truemper Street, Lackland AFB TX 78236–5511 or via e-mail at *737TRG.CCE@Lackland.af.mil.*

Request must contain name and Social Security Number (SSN).

CONTESTING RECORDS PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Personal data on recruits is received electronically from the Technical Training Management System (TTMS). Training data is input by personnel assigned to the 737th Training Group.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26775 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2008–0079]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to Amend a System of Records.

SUMMARY: The Department of the Army is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Department of the Army, Freedom of Information/Privacy Division, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905.

FOR FURTHER INFORMATION CONTACT: Ms. Vicki Short at (703) 428–6508.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0381–100a DAMI

SYSTEM NAME:

Intelligence/Counterintelligence Source Files (November 1, 1995, 60 FR 51996).

CHANGES:

* * * * *

STORAGE:

Delete entry and replace with ''Paper records and electronic storage media.''

* * * * *

SAFEGUARDS:

Delete entry and replace with ''Buildings employ alarms, security guards and/or rooms are security controlled accessible only to authorized persons. Paper records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically stored records are maintained in specialized software with password protected access and data backup measures. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Records are retained in active file until no longer needed; then retired to the IRR where they are destroyed 75 years after date of last action. Destruction is by shredding, burning, or pulping for paper records and magnetic erasing for electronic records.''

* * * * *

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Intelligence and Security Command, Freedom of Information/Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, any alias, Social Security Number (SSN), date and place of birth, current address, telephone number and notarized signature.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Intelligence and Security Command, Freedom of Information/Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, any alias, Social Security Number (SSN), date and place of birth, current address, telephone number and notarized signature.''

* * * * *

A0381–100a DAMI

SYSTEM NAME:

Intelligence/Counterintelligence Source Files.

SYSTEM LOCATION:

U.S. Army Intelligence and Security Command, 8825 Beulah Street, Fort Belvoir, VA 22060–5246.

Decentralized segments are located at U.S. Army Intelligence brigades, groups, battalions, companies, detachments, and field offices and resident offices worldwide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Selected individuals who qualify and may be accepted as an intelligence or counterintelligence source for the U.S. Army.

CATEGORIES OF RECORDS IN THE SYSTEM:

Record consists of agreements; contracts; information reports; financial reports; operational correspondence; requests for, technical files, and results of polygraph examinations; audiovisual products and similar documents necessary to confirm operational use of source or future claims against the Army by source or heirs of the source. Administrative records required by the U.S. Army Investigative Records Repository (IRR) for records management purposes such as form transmitting operational material to the IRR and providing instructions for indexing the record in the Defense Central Index of Investigations [Defense Clearance and Investigations Index] (System Notice V5–02) and release of material contained therein, form indicating dossier has been reviewed and all material therein conforms to Department of Defense (DoD) policy regarding retention criteria, form pertaining to the release of information pertaining to controlled records, cross reference sheet to indicate the removal of investigative documents requiring limited access, form identifying material that has been segregated and or is exempt from release, and records accounting for the disclosure of operational information made outside of the DoD.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; National Security Act of 1947, as amended; E.O. 10450, Security Requirements for Government Employment, paragraphs 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.O. 12333, United States Intelligence Activities, paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; the National Security Act of 1947, as amended; the Intelligence Authorization Act of 1995, title V, section 503 and title VIII, sections 801–811 and E.O. 9397 (SSN).

PURPOSE(S):

To support contingency planning and military operations, to conduct counterintelligence and intelligence operations, to confirm claims against the Army by source or heirs of source, and to document source operations pertaining to the U.S. Army's responsibilities for intelligence and counterintelligence.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as routine uses pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

By individual name or source/project name, date and place of birth, Social Security Number, and numerically by source or project number.

SAFEGUARDS:

Buildings employ alarms, security guards and/or rooms are security controlled accessible only to authorized persons. Paper records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically stored records are maintained in specialized software with password protected access and data backup measures. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.

RETENTION AND DISPOSAL:

Records are retained in active file until no longer needed; then retired to the IRR where they are destroyed 75 years after date of last action. Destruction is by shredding, burning, or pulping for paper records and magnetic erasing for electronic records.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Intelligence, Headquarters, Department of the Army, 1001 Army Pentagon, Washington, DC 20310–1001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Intelligence and Security Command, Freedom of Information/ Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, any alias, Social Security Number (SSN), date and place of birth, current address, telephone number and notarized signature.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Intelligence and Security Command, Freedom of Information/ Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, any alias, Social Security Number (SSN), date and place of birth, current address, telephone number and notarized signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From individual; Federal and Department of Defense investigative, intelligence and law enforcement agencies; and foreign investigative, intelligence, and law enforcement agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5), as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 505. For additional information contact the system manager.

[FR Doc. E8–26754 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare an Environmental Impact Statement for Basewide Utility Infrastructure Improvements at Marine Corps Base (MCB) Camp Pendleton, San Diego County, CA

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: In accordance with section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4332(2)(c)), as implemented by the Council on Environmental Quality Regulations (40 CFR parts 1500–1508), the Department of the Navy intends to prepare an environmental impact statement (EIS) and conduct a public scoping meeting for the proposed construction, installation, and operation of multiple utility infrastructure improvements throughout MCB Camp Pendleton in San Diego County, California.

DATES: The Department of the Navy will review all comments received during the 30-day public scoping period, which starts with the publication of this Notice of Intent. The public scoping meeting will be held in the San Clemente Community Center, 100 North Calle Seville, San Clemente, California, 92672 from 6 p.m. to 8 p.m. on December 10, 2008.

ADDRESSES: Written comments on the scope of the MCB Camp Pendleton Basewide Utility Infrastructure Improvements EIS should be directed to: Ms. Rebecca Loomis, Naval Facilities Engineering Command Southwest, 1220 Pacific Highway, San Diego, California, 92132.

FOR FURTHER INFORMATION CONTACT: Ms. Rebecca Loomis, Naval Facilities Engineering Command Southwest at *telephone:* 619–532–3728, *fax:* 619–532–4160, or *e-mail: rebecca.l.loomis@navy.mil.*

SUPPLEMENTARY INFORMATION: The purpose of the proposed action is to provide reliable, new, expanded, compliant utility systems to support Military Training and Operations and delivery of life support and quality of life services. The proposed action will also provide system redundancy that will enable the delivery of utility services during periods of scheduled and unscheduled/emergency outages. The proposed action is needed to modernize and expand Camp Pendleton's aging (1940s/50s era) utility systems and infrastructure in order to:

(1) Sustain compliance with current and future regulatory and code requirements, (2) provide reliable services and alternate sources for planned maintenance and unscheduled repairs, and to assure availability during periods of emergency and natural disaster, (3) conserve and effectively manage resources, and (4) accommodate current and potential future growth at MCB Camp Pendleton. The proposed action consists of eight projects, which are discussed below.

Northern Regional Tertiary Treatment Plant (NRTTP) and Associated Facilities (MILCON P–1043)

P–1043 would construct a 5-million-gallon per day NRTTP and sludge treatment facility near the location of existing Sewage Treatment Plant (STP) 11. This project consolidates and replaces the existing Sewage Treatment Plants (STP) 10, 11, and 12 and would treat raw sewage from the associated collection system and conveyance lines. In order to accomplish this, the project would include modification or reuse of the existing headworks facilities at STPs 10, 11, and 12; a new sewer conveyance line from STP 12 in San Mateo (62 Area) to the new NRTTP; lift stations, and the conversion of STP 12 to a Tributary Area Pump Station (TAPS). The new NRTTP will include various sewage treatment components within the plant compound such as: an influent pump station, sludge treatment and handling facilities, preliminary treatment facilities, secondary treatment facilities, advanced (tertiary) wastewater treatment facilities, chemical storage and feed systems, odor control facilities, and a 4,600-square-foot operations facility. Some demolition may be required as part of the conversion of STPs 10, 11, and 12 to TAPS.

P–1043 would construct approximately 36,000 linear feet (LF) of wastewater main lines sized from 8 to 15 inches in diameter. The project would begin in Talega (64 Area) and would continue through Cristianitos (63 Area) to the proposed TAPS 12 at San Mateo (62 Area). The project would provide new wastewater lines to replace the existing wastewater lines from the San Onofre Housing area to the proposed NRTTP. A new wastewater line would also replace the existing wastewater line from Horno (53 Area) through the School of Infantry (52 Area) to the proposed NRTTP. The project would also construct approximately 70,000 LF of pipeline from the NRTTP to convey recycled water to selected reuse areas in Talega (64 Area). The project would include new Reuse Pump Stations, a 2-million-gallon NRTTP reuse water storage facility, and backflow preventors to prevent any cross connections between the potable and wastewater systems.

Alternatives—The alternative for P–1043 would be an alternative alignment from San Mateo (62 Area) to STP 11. This alignment would extend the line from STP/TAPS 12 south along Coast Road, east of the northern agriculture fields and to Basilone Road, and then east along Basilone Road to STP 11. This alignment would follow the alignment for P–1045 discussed below. Also, the use of Horizontal Directional Drilling (HDD) for passing under San Mateo Creek will also be considered as a feasible technology. This will be compared to more standard pipe laying construction methods such as trenching and backfilling.

Advanced Water Treatment (AWT) North and Associated Facilities (MILCON P–1044)

P–1044 would construct AWT facilities to serve the northern region of MCB Camp Pendleton to provide a reduction of total dissolved solids, total organic carbon, and corrosivity. Construction would include a Granulated Activated Carbon/Reverse Osmosis facility and associated Brine Disposal System. Micro-filtration system is used for water treatment. The Brine Disposal System would connect the Reverse Osmosis module and would include a brine/slurry dilution facility, brine line pump station, and pipeline to an ocean outfall at San Onofre Nuclear Generating Station (SONGS). The project would also construct wellhead collection points with associated piping and pumps and an 800-square-foot operations facility. P–1044 would construct approximately 59,000 LF of main water lines, with pipelines ranging in size from 10 to 14 inches in diameter for potable water conveyance in the northern region of MCB Camp Pendleton. The new lines would connect into the new AWT Facility North. The line would begin at the AWT facility in the San Onofre Housing Cantonment area and continue to Horno (53 Area). A second water line would link Talega (64 Area) to San Mateo (62 Area). The project would include three pump stations with emergency generators, asphalt patches, and connection to existing reservoirs and distribution system. Potable water loops, 8-inch in diameter would be installed within each cantonment and housing area totaling approximately 21,000 LF of piping.

Alternative—Alternatives would include consideration of multiple independent raw water treatment facilities and feasible treatment technologies located within multiple cantonment areas instead of consolidated regional treatment plants.

Connection of North and South Water Systems (MILCON P–1045)

P–1045 would construct approximately 90,000 LF of potable waterlines sized approximately 36 inches in diameter to connect the northern and southern water systems of MCB Camp Pendleton. A water line would begin at the proposed AWT Facility (P–1044), extend past the SONGS Mesa facility, and then continue along the east side of Interstate 5 (I–5) before crossing San Onofre Creek. The line would travel south along Stuart Mesa Road, cross the Santa Margarita River, and then would connect to the southern water system at the intersection of Stuart Mesa Road and Vandegrift Boulevard. The project would also include three pump stations at the north, central, and south portions of the Base to connect Las Pulgas, Las Flores, and the Stuart Mesa areas to the South Water System.

Alternative Alignment—This alternative alignment would begin at the proposed AWT facilities (P–1044) and extend east along Basilone Road (instead of El Camino Real) to Las Pulgas Road and then south on Las Pulgas Road to Stuart Mesa Road. At Stuart Mesa Road the alignment would follow the same alignment of the proposed action to the connection of the southern system at the corner of Stuart Mesa Road and Vandegrift Boulevard. Also, the project would consider the use of approximately 7,000 LF of HDD beneath San Onofre Creek and the Santa Margarita River.

Upgrades to Electrical Systems and Associated Facilities (MILCON P–1048)

P–1048 would construct a 69 kilovolt (kV) electrical transmission system that will provide a more efficient and reliable transmission method, system redundancy and energy cost savings. The 69 KV system will meet industry standard for long distance delivery of power and provide capability to back feed all cantonment areas from a secondary source during blackouts caused by wildfires, other natural disasters, and/or systems failure. The project would construct four new 69 kV substations located (1) at the existing Haybarn Canyon location, (2) near the intersection of Pulgas Road and Stuart Mesa Road, (3) in the vicinity of the SONGS, and (4) in the general area of the intersection of Cristianitos Road and San Mateo Road. The first three substations would connect to existing

San Diego Gas and Electric (SDG&E) 69 kV lines. The fourth substation would convert the proposed MCB Camp Pendleton 69 kV line to the existing MCB Camp Pendleton 12 kV system. The project would provide distribution of electrical power through four different connecting segments. The first segment (Haybarn segment) would include a new 69 kV overhead distribution line with a 12 kV line running on the same utility poles. These lines would connect the proposed Substation #1 to Range 409. For the second segment, the 69 kV distribution line would extend underground (to avoid conflicts with aircraft training and safety) through Range 409 to resurface in the eastern portion of the Base. For the third segment, the 69 kV distribution line would continue overhead along the eastern and northern Base boundaries following the SDG&E 230 kV transmission lines, proceed down Cristianitos Road and connect to the proposed Substation #4, and continue to I–5. The line would parallel I–5 toward the proposed Substation #3 located in the vicinity of SONGS, completing the northern loop. For the fourth segment, the final 69 kV overhead power line would extend from the proposed Substation #2 and follow Pulgas Road with a 69 kV and 12 kV distribution line on the same utility pole. At Las Pulgas (43 Area), only the 69 kV line would continue south along Basilone Road to Roblar Road to connect to the Haybarn line, completing the southern loop.

Alternative Alignment—The alternative to P–1048 would be to underground all four electrical line segments. Under the proposed action only the segment through Range 409 is proposed to be underground.

MILCON P–1094

P–1094 would replace the existing 12 kV electrical distribution systems currently fed from the Haybarn substation, and the 4.16 kV subsystems fed from the 12 kV distribution system. The project would construct a total of 8 new 12 kV circuits, which would be fed from the new 69 kV substation (P–1048), to provide approximately 60 percent of the electrical power for MCB Camp Pendleton. Existing ''A'' circuit provides power to the 11, 12, 13, 15, and 16 (Mainside) areas of MCB Camp Pendleton. Existing ''C'' circuit would provide power to the 23 (Marine Corps Air Station Camp Pendleton (MCAS CP)), 25 Vado del Rio), 32 (MASS–3), and 33 (Margarita) areas. Existing ''E'' circuit would provide power to the 20 (Main Gate), 22 (Chappo), and 26 (at the bottom of Rattlesnake Canyon Rd) areas and would also provide power to the housing areas at Wire Mountain. Existing ''F'' circuit would provide power to the 26 Area and the Naval Hospital. Existing ''G'' circuit would provide power to the 14 and 15 (Mainside) areas, O'Neil Housing, Camp Day, and Range 409. Existing ''H'' circuit would provide power to the 23 (MCAS CP) and 24 (Pico) areas. The project would provide replacement 12 kV circuits for the existing ''A,'' ''C,'' ''E,'' ''F,'' ''G,'' and ''H'' circuits and would provide new circuits to supply power to 21 Area (Del Mar) and the 31 Area (Edson Range and Assault Craft Unit-5). Overhead distribution lines would include aluminum core steel reinforced wire and both 45-foot and 70-foot tall wood poles, with crossarms and insulators. Underground distribution lines would include copper insulation, 4 to 6-inch polyvinyl chloride conduit, trenching, pavement cutting, utility vault placement, conduit placement, grounding, concrete encasement, and asphalt pavement patching.

Alternative Alignment—Similar to the alternative for P–1048, the alternative for P–1094 would be to underground the proposed electrical lines.

Wastewater Facilities, Roadway Improvements, and Shoot House Construction and Expansion (MILCON P–1049)

P–1049 would construct approximately 20,000 LF of potable water and sanitary sewer utilities, including new sewer lines, manholes, cleanouts, and a lift station, to better house and train Marines at the Range 130 Complex in the X-Ray Training Area. P–1049 would also include approximately 3 miles of roadway improvements, including 10-inch base material, track mix asphalt surface course, and culverts at established drainage points. Other facilities proposed include a 2,500-square-foot shoot house and a 24,000-square-foot covered small arms range. The project would also enlarge an existing covered small arms range to approximately 34,000 square feet.

Alternative Alignment—This alignment would extend from the preferred alignment along the main access road to Range 130, west to the pump station in the 41 Area instead of continuing along the main access road southwest to Stuart Mesa Road. This would reduce the overall pipe length by approximately 3,000 LF.

Communication Upgrades (MILCON P–1093)

P–1093 would provide both intercamp and intracamp fiber-optic cable and telephone cable connections. This project would provide a redundant communications network by providing a minimum of two separate communication line paths to each area on the Base.

Alternatives—Potential alternatives for P–1099 include placing all communication lines overhead. Another alternative to be addressed would include the use of wireless communication instead of landline communication.

Natural Gas System Upgrades (MILCON P–1099)

P–1099 installs new high pressure 6 inch High Density Polyethylene (HDPE) gas mains in four separate locations: (1) Approximately 15,000 LF from 62 (San Mateo) Area to 63 (Christainitos) Area and to 64 (Talega) Area (currently the 63 and 64 Cantonment Areas are only supplied by propane gas storage tanks), (2) approximately 30,000 LF from 41 Area to 43 Area, (3) approximately 30,000 LF from 43 Area to 25 Area (interconnecting the southern and northern natural gas systems, and (4) approximately 15,000 LF from the Naval Hospital to the Headquarters Area (providing the Naval Hospital with back-up source of natural gas). Construction would consist of saw cutting existing asphalt concrete pavement, trench excavation, and installation of new HDPE pipe including fittings, etc. P–1099 would also include patching of existing pavement and related roadway lane striping and traffic control.

Alternative Alignment—The alternative alignment for P–1099 would extend the proposed natural gas the line from the Naval Hospital east through undeveloped land directly to De Luz Road.

Preliminary Alternatives

The EIS will address the proposed utility alignments, alternative utility segment alignments, and alternative alignment installation (aboveground, underground) as briefly discussed above. In addition, alternative technologies, including multiple smaller systems; and the No Action Alternative will be addressed.

Environmental Issues and Resources To Be Examined

The EIS will evaluate the potential environmental effects associated with each of the alternatives. Issues to be addressed include, but are not limited to, biological resources, historic and archaeological resources, geology and soils, hydrology, water quality, air quality, visual resources, and public

services. Relevant and reasonable measures that could alleviate environmental effects will be identified and considered.

Other Agency Involvement

The Department of the Navy will undertake necessary consultations with regulatory entities pursuant to the Endangered Species Act, Clean Water Act, National Historic Preservation Act, and any other applicable law or regulation. Consultation will include but is not limited to the following federal, state, and local agencies: U.S. Fish and Wildlife Service; State Historic Preservation Officer; American Indian Tribes; U.S. Army Corps of Engineers; U.S. Environmental Protection Agency; all local Historic Site Boards and Heritage organizations; California Regional Water Quality Control Board; California Coastal Commission; San Diego Air Pollution Control District; and the County of San Diego, Department of Environmental Health.

Public Scoping Process: The Department of the Navy is initiating the scoping process to identify community concerns and local issues that should be addressed in the EIS. Federal, State, and local agencies and interested persons are encouraged to provide oral and/or written comments to identify specific issues or topics of environmental concern for consideration in the EIS. The Navy will consider these comments in determining the scope for the EIS. The public scoping period begins with the publication of this Notice of Intent, and will continue for 30 days, ending on December 15, 2008. Written comments on the scope of the EIS should be submitted no later than December 15, 2008 by mail to Ms. Rebecca Loomis, Naval Facilities Engineering Command, Southwest, 1220 Pacific Highway, San Diego, California 92132 or e-mail to *Rebecca.l.loomis@navy.mil.* The public scoping meeting will be held in the San Clemente Community Center, 100 North Calle Seville, San Clemente, California 92672 from 6 p.m. to 8 p.m. on December 10, 2008. The meeting also will be announced by notices published in the North County Times and San Clemente Times 15 days prior to the scoping meeting. A court reporter will be available at the meeting to accept oral comments.

Dated: November 5, 2008.

T. M. Cruz,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–26817 Filed 11–10–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2008–0057]

Privacy Act of 1974; System of Records

AGENCY: U.S. Marine Corps, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The U.S. Marine Corps is proposing to add a new system of records notice to its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008, unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to Headquarters, U.S. Marine Corps, FOIA/PA Section (ARSF), 2 Navy Annex, Room 3134, Washington, DC 20380–1775.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Ross at (703) 614–4008.

SUPPLEMENTARY INFORMATION: The U.S. Marine Corps system of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a, of the Privacy Act of 1974, as amended, was submitted on October 24, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

M–01080–1

SYSTEM NAME:

Total Force Administration System Secure Personnel Accountability (TFAS SPA) Records.

SYSTEM LOCATION:

Web servers will be located at Information Systems Management Branch (ARI), Headquarters Marine Corps, #2 Navy Annex, Washington, DC 20380–1775. The Cross Domain Solution (CDS) server will be located at the Defense Information Support Agency (DISA), 701 South Courthouse Road, Arlington, VA 22204–2199.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Deployed active duty Marines, as well as DoD members who are under the status of United States Code Title 10 Armed Forces Operational Control (OPCON) and Administrative Control (ADCON) to Marine Force Commands to include Army National Guard, and reserve military service members of the Air Force, Navy, Army, and approved foreign military personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Deployed service data such as: current location (Country, Area of Operation, Military Grid, Lat/Long, etc.), Title 10 OPCON, Title 10 ADCON, assigned, attached, tenant command relationships; full name, rank, Social Security Number (SSN), date of birth, sex, death date, marital status, citizenship, country code, personnel category code, personnel entitlement condition type code, service, primary occupation code, and pay plan code. The system contains specific unit information (commander name and unit location), for the personnel it tracks.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; CJCSM 3150.13B Joint Reporting Structure—Personnel Manual; Title 10 U.S.C. 136, Uniform Code of Military Justice; and E.O. 9397 (SSN).

PURPOSE(S):

The TFAS SPA Module provides a tool to implement deployed accountability for all active duty U.S. Marines, as well as DoD members who are Title 10 OPCON to Marine Force Commands to include Army National Guard, and reserve military service members of the Air Force, Navy, Army, and approved foreign military personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To officials and employees of other departments and agencies of the Executive Branch of government, upon request, in the performance of their

official duties related to the management of deployed Marine individuals at locations worldwide, as well as officials and investigating bodies for health surveillance purposes.

The 'Blanket Routine Uses' that appear at the beginning of the Marine Corps' compilation of systems of records notices also apply to this system. The ''Blanket Routine Uses'' appear at *http://www.privacy.navy.mil/*.

Marine Forces delegated Title 10 operational control (OPCON) authority from a U.S. Armed Forces Combatant command. The Office of Secretary of Defense (OSD) has mandated that Marine operational forces are responsible to report the location of all Service Members' classified location under Marine Forces' command worldwide.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Name and/or Social Security Number and/or Unit.

SAFEGUARDS:

Records are maintained in areas only accessible to authorized ARI personnel that are properly screened, cleared, and trained. System software uses a user name and password challenge to lock out unauthorized access. System software contains authorization permission lists and role partitioning to limit access to appropriate organizational level.

RETENTION AND DISPOSAL:

The records retention has not been approved by The National Archives and Records Administration, until then treat as permanent.

SYSTEM MANAGER AND ADDRESS:

Policy Official and Records Holder is Director, Manpower Information (MI), 3280 Russell Rd., Quantico, VA 22134–5103.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to Director, Manpower Information (MI), 3280 Russell Rd., Quantico, VA 22134–5103.

Your request must be signed and include your full name and SSN, as well as your complete mailing address.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to Director, Manpower Information (MI), 3280 Russell Rd., Quantico, VA 22134–5103.

Your request must be signed and include your full name and SSN, as well as your complete mailing address.

CONTESTING RECORD PROCEDURES:

The USMC rules for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; Marine Corps Order P5211.2; 32 CFR part 701; or may be obtained from the system manager, Director, Manpower Information (MI), 3280 Russell Rd., Quantico, VA 22134–5103.

RECORD SOURCE CATEGORIES:

Name, SSN, and associated personnel data is pulled from the Operational Data Store Enterprise (ODSE) and Defense Manpower Data Center (DMDC).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Information specifically authorized to be classified under E.O. 12958, as implemented by DoD 5200.1–R, may be exempt pursuant to 5 U.S.C. 552(k)(1).

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) published in 32 CFR part 701. For additional information contact the system manager.

[FR Doc. E8–26757 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2008–0056]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to Add a System of Records.

SUMMARY: The Department of Navy proposes to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on December 12, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Department of the Navy, 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Miriam Brown-Lam at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on October 21, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals'', dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM01500–3

SYSTEM NAME:

Advanced Skills Management (ASM) System Records.

SYSTEM LOCATION:

Naval Undersea Warfare Center, Keyport, 610 Dowell Street, Keyport, WA 98345–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps military, government and contractor personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, branch of service, rate/rank with effective date, date of birth, social security number, billet, expiration of active obligated service, duty station, driver's license information, medical exam results, job skill sets; training qualifications and certification records; training tests taken and scores, remedial training requirements, On the Job Training (OJT) record, Navy Enlisted Classification, USMC Military Occupational Specialty, subspecialty codes, and other records of educational and professional accomplishment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Commandant Marine Corps, and E.O. 9397 (SSN).

PURPOSE(S):

To maintain automated records concerning training, education, and qualifications of Navy and Marine Corps military, government and contractor personnel for use by Manpower, Personnel and Training (MPT) managers.

To maintain an Electronic Training Jacket to assess individual training requirements and readiness, manage Navy and Marine Corps formal, general military and technical training, qualifications, certifications and licenses, and create short and long term training action plans for individuals. Contains master task lists, tests and evaluation modules.

To allow for the evaluation/assessment of assigned personnel training requirements and readiness, automates unit training readiness assessments, and a determination of unit readiness percentage at the unit level.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Access to the application is controlled by Common Access Card (CAC), Public Key Enabled for Server Side Certificate Based Authentication, using DOD PKI Server Certificates and Secure Sockets Layer (SSL) Session Encryption. Once authenticated into ASM, access to a specific database is controlled by unique user ID and password. ASM Database servers are maintained in limited access areas accessible only to authorized personnel with the appropriate level of clearance, and who are properly trained. Physical access to server rooms and buildings are controlled by approved locks. Server and database administration will be restricted to approved personnel, utilizing role-based administration of users, groups and security permissions.

RETENTION AND DISPOSAL:

Records are destroyed one year after discontinued service.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding Officer, Naval Undersea Warfare Center, 610 Dowell Street, Keyport, WA 98345–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should write to the Commanding Officer, Naval Undersea Warfare Center, 610 Dowell Street, Keyport, WA 98345–5000.

Requests should include full name, Social Security Number (SSN), and must be signed by the requesting individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should contact the Commanding Officer, Naval Undersea Warfare Center, 610 Dowell Street, Keyport, WA 98345–5000.

Requests should include full name, Social Security Number (SSN), and must be signed by the requesting individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5, 32 CFR part 701, or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual; Training Jackets; Navy Training Management and Planning System (NTMPS); Enlisted Distribution Verification Report; Naval Aviation Logistics Command Maintenance Information System (NALCOMIS); Reserve Unit Assignment Document (RUAD); and Alpha Rosters.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26777 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2008–0058]

Privacy Act of 1974; System of Records

AGENCY: U.S. Marine Corps, DoD.

ACTION: Notice to Add a System of Records.

SUMMARY: The U.S. Marine Corps is proposing to add a new system of records notice to its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on December 12, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to Headquarters, U.S. Marine Corps, FOIA/PA Section (ARSF), 2 Navy Annex, Room 3134, Washington, DC 20380–1775.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Ross at (703) 614–4008.

SUPPLEMENTARY INFORMATION: The U.S. Marine Corps system of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a, of the Privacy Act of 1974, as amended, was submitted on October 30, 2008, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 3, 2008.

Morgan E. Frazier,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

M01754–5

SYSTEM NAME:

Marine Corps Family Readiness Mass Communication Records.

SYSTEM LOCATION:

Primary location: The Marine Corps Community Services (MCCS) contractor secured site—3n Global, Incorporated, 505 N. Brand Boulevard, Suite 700, Glendale, CA 91203.

Secondary locations: Commandant of the Marine Corps, Headquarters, U.S. Marine Corps, Marine Corps Community Services, 3280 Russell Road, MCB Quantico, VA 22134–5009, and Marine Corps Community Services (MCCS) offices located at Marine Corps installations. Official MCCS offices mailing addresses are published on the MCCS Web site at *http://www.usmc-mccs.org/downloads/mccsdir.pdf.*

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active Duty and Reserve military officer and enlisted personnel assigned

to Marine Corps units/activities, dependents, and other individuals designated as personal contacts.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, home addresses, work addresses, contact telephone numbers, contact e-mail addresses, relationship information, and the last four digits of the military members' Social Security Number (SSN).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013; Secretary of the Navy; 10 U.S.C. 5041, Headquarters, U.S. Marine Corps; MCO 1754.6A and NAVMC 1754.6A, Marine Corps Family Team Building; and E.O. 9397 (SSN).

PURPOSE(S):

To effect clear and direct communication between Marine Corps family readiness officers and military members, their family members, and other individuals designated by the military member, in order to ensure family preparedness and readiness before, during, and after a military member's deployment and related absence from the family. Note that this tool will not be used to communicate casualty notification or assistance information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows: The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

Name and last four digits of the military member's SSN or the name and relationship for individuals other than military members.

SAFEGUARDS:

Password controlled system, file, and element access based on predefined need-to-know basis. Computer facilities and terminals are located in restricted areas accessible only to authorized persons that are properly screened, cleared and trained. Manual records and computer printouts are available only to authorized personnel having a need-to-know. Data is encrypted while at rest and during transmission.

Physical access to terminals, terminal rooms, buildings and activities' grounds are controlled by locked terminals and rooms, guards, personnel screening, or visitor registers.

RETENTION AND DISPOSAL:

Per SECNAV M–5210.1, disposition for these records is unauthorized. Records will not be destroyed until a disposition is approved.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Manager: Commandant of the Marine Corps, Headquarters, U.S. Marine Corps, Marine Corps Community Services, 3280 Russell Road, MCB Quantico, VA 22134–5009.

Secondary Managers: Directors of Marine Corps Community Services (MCCS) offices. Official mailing addresses are published on the MCCS Web site at *http://www.usmc-mccs.org/downloads/mccsdir.pdf.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the MCCS office servicing the activity where the Marine is currently stationed. Official mailing addresses are published on the MCCS Web site at *http://www.usmc-mccs.org/downloads/mccsdir.pdf.*

The written inquiry should include the individual's full name, the last four digits of their Social Security Number (SSN), and written signature.

RECORD ACCESS PROCEDURE:

Individuals seeking to access information about themselves contained in this system should address written inquiries to the MCCS office servicing the activity where the Marine is currently stationed. Official mailing addresses are published on the MCCS Web site at *http://www.usmc-mccs.org/downloads/mccsdir.pdf.*

The written inquiry should include the individual's full name, the last four digits of their Social Security Number (SSN), and written signature.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals, military personnel record files, and/or the Marine Corps Total Force System database.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–26778 Filed 11–10–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 12, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility,

and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 5, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Safe and Drug Free Schools

Type of Review: Revision.

Title: Gun-Free Schools Act Report.

Frequency: Annually.

Affected Public: Businesses or other for-profit; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 7,221.

Burden Hours: 14,756.

Abstract: The Gun-Free Schools Act (GFSA) requires States to provide annual reports to the Secretary of Education concerning implementation of the GFSA's requirements based on information collected from local educational agencies (LEAs) in their applications requesting assistance. The GFSA requires each State receiving ESEA funds to have in effect a State law requiring LEAs to expel from school for a period of not less than one year a student found to have brought a firearm to school or to have possessed a firearm at school. The GFSA also requires LEAs that receive ESEA funds to adopt a policy requiring referral to the criminal justice or juvenile delinquency system of any student who brings a firearm to school or possesses a firearm at school.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3854. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–26785 Filed 11–10–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 12, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 5, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Innovation and Improvement

Type of Review: New Collection.

Title: Transition to Teaching Evaluation.

Frequency: Other: At the end of the third year and end of final year of the TTT grant.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 135.

Burden Hours: 45.

Abstract: This is a request for approval to collect information from Transition to Teaching (TTT) grantees that will be used to describe the extent to which local education agencies that received TTT grant funds have met the goals relating to teacher recruitment and retention described in their application. TTT grantees are funded for a period of five years. Currently, grantees are required by statute to submit an interim project evaluation to ED at the end of the third project year and a final project evaluation at the project's end. In turn, the TTT program is required to prepare and submit to the Secretary and to Congress interim and final program evaluations containing the results of these grantee project evaluation reports. An analysis of these reports has provided some data on grantee activities, but the poor quality of some reports and missing or incomplete data in others have made it difficult to aggregate data across grantees in order to accurately describe to Congress the extent of program implementation. This proposed data collection would allow ED to gather data on a common set of indicators across grantees to describe program implementation, and to investigate the conditions under which projects have been successful at recruiting, preparing and retaining highly qualified teachers in high-need schools in high-need LEAs.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3908. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW.,

LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–26819 Filed 11–10–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, December 4, 2008, 9 a.m.–5 p.m.

Friday, December 5, 2008, 8:30 a.m.–4 p.m.

ADDRESSES: Red Lion Hotel, 802 George Washington Way, Richland, Washington 99252, *Phone:* (509) 946–7611, *Fax:* (509) 943–8564.

FOR FURTHER INFORMATION CONTACT: Paula Call, Federal Coordinator, Department of Energy Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, A7–75, Richland, WA 99352; *Phone:* (509) 376–2048; or *e-mail: Paula_K_Call@rl.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

- Agency Updates (Department of Energy Office of River Protection and Richland Operations Office; Washington State Department of Ecology; and the U.S. Environmental Protection Agency).
- Update on Tri-Party Agreement negotiations.
- Briefings on new contracts, contractors, and the transition process.
- Discussion on the outcome of the November 19, 2008, Department of Energy. Baseline Workshop.
- Update on the Hanford site-wide safety program.
- Discussion on the outcome of the October 30, 2008, Sing-Shell Tank Integrity Expert Panel managers meeting.
- Hanford Advisory Board member and issue manager training.
- Committee Updates, including: Tank Waste Committee; River and Plateau Committee; Health, Safety and Environmental Protection Committee; Public Involvement Committee; and Budgets and Contracts Committee.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Paula Call's office 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. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Paula Call's office at the address or phone number listed above. Minutes will also be available at the following Web site: *http://www.hanford.gov/?page=413&parent=397.*

Issued at Washington, DC, on November 5, 2008.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E8–26848 Filed 11–10–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

International Energy Agency Meetings

AGENCY: Department of Energy.

ACTION: Notice of meetings.

SUMMARY: The Industry Advisory Board (IAB) to the International Energy Agency (IEA) will meet on November 19, 2008, at the headquarters of the IEA in Paris, France, in connection with a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market on November 19, and on November 20 in connection with a meeting of the SEQ on November 20.

DATES: November 19–20, 2008.

ADDRESSES: 9, rue de la Fédération, Paris, France.

FOR FURTHER INFORMATION CONTACT: Diana D. Clark, Assistant General Counsel for International and National Security Programs, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, 202–586–3417.

SUPPLEMENTARY INFORMATION: In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)) (EPCA), the following notice of meeting is provided:

Meetings of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held at the headquarters of the IEA, 9, rue de la Fédération, Paris, France, on November 19, 2008, beginning at 9:30 a.m. and at 8:30 a.m. on November 20. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market (SOM) on November 19 beginning at 9:30 a.m. at the same location. The IAB will also hold a preparatory meeting among company representatives at the same location at 8:30 a.m. on November 20. The agenda for this preparatory meeting is to discuss the November 19 joint meeting of the SEQ and the SOM and to review the agenda for the SEQ meeting commencing at 9:30 a.m. on November 20.

The agenda of the joint SEQ/SOM meeting on November 19 is under the control of the SEQ and the SOM. It is expected that the SEQ and the SOM will adopt the following agenda:

1. Adoption of the Agenda
2. Approval of the Summary Record of the September 2008 SEQ/SOM Joint Session
3. The Current Oil Market Situation
4. Update on the Gas Market
5. The Medium-Term Outlook for the Products Market
6. *The World Energy Outlook 2008:* The Long-Term Outlook for the Oil Market
7. Developments on Recent Oil Market and Policy Developments in IEA Member Countries
8. Update on London/Jeddah Meetings
9. Dire Straits (Risk Affecting Chokepoints)
   —The Strait of Hormuz
   —The Strait of Malacca
   —Consequences for the Tanker Market
10. Other Business

The agenda of the SEQ meeting on November 20, 2008, is under the control of the SEQ. It is expected that the SEQ will adopt the following agenda:

1. Adoption of the Agenda
2. Approval of the Summary Record of the 124th Meeting
3. Status of Compliance with IEP Stockholding Commitments
4. Emergency Response Review Program
—Questionnaire Response of Italy
—Questionnaire Response of Portugal
—Schedule of Emergency Response Reviews
5. Emergency Response Exercise
—Plan for Future Emergency Response Exercises
—Proposal for Workshop on Best Practices for Release of Public Stocks
6. Policy and Other Developments in Member Countries
—Australia
—Canada
7. Activities with International Organizations and Non-Member Countries
—Update on the Revised EU Directive on Emergency Oil Stocks
—Work on Candidate Countries
—Emergency Response Exercises in Thailand, China, and India
8. Report from the Industry Advisory Board
9. Emergency Policy for Natural Gas
10. Emergency Data Collection
—Final Evaluation of the Use of QuE (Emergency Data Questionnaire) During the Exercise in Capitals
11. Documents for Information
—Emergency Reserve Situation of IEA Member Countries on July 1, 2008
—Base Period Final Consumption: 4Q 2007–3Q 2008
—Monthly Oil Statistics: August 2008
—Emergency Contacts List
12. Other Business
—New SEQ Website
—New Division E-Mail Address
—Tentative Schedule of Meetings
—March 24–26, 2009
—June 23–25, 2009
—November 17–19, 2009

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(ii)), the meetings of the IAB are open to representatives of members of the IAB and their counsel; representatives of members of the IEA's Standing Group on Emergency Questions and the IEA's Standing Group on the Oil Markets; representatives of the Departments of Energy, Justice, and State, the Federal Trade Commission, the General Accounting Office, Committees of Congress, the IEA, and the European Commission; and invitees of the IAB, the SEQ, the SOM, or the IEA.

Issued in Washington, DC, November 5, 2008.

Diana D. Clark,

Assistant General Counsel for International and National Security Programs.

[FR Doc. E8–26859 Filed 11–10–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. DI09–2–000]

Alaska Power & Telephone Company; Notice of Declaration of Intention and Soliciting Comments, Protests, and/or Motions To Intervene

November 4, 2008.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Declaration of Intention.

b. *Docket No:* DI09–2–000.

c. *Date Filed:* October 28, 2008.

d. *Applicant:* Alaska Power & Telephone Company.

e. *Name of Project:* Connelly Lake Hydroelectric Project.

f. *Location:* The proposed Connelly Lake Hydroelectric Project will be located on Connelly Lake, an unnamed stream, and the Chilkoot River, near the towns of Haines and Skagway, Haines Borough, Alaska, affecting T. 28 S, R. 57 E, secs. 22, 26, 27, 34, 35, and 36, and T. 29 S, R. 58 E, secs. 4, 5, 9, 10, 14, 15, 22, 23, 25, and 26, Copper River Meridian.

g. *Filed Pursuant to:* Section 23(b)(1) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Glen D. Martin, Project Manager, 193 Otto Street, P.O. Box 3222, Port Townsend, WA 98368, *telephone:* (360) 385–1733, x122; *Fax:* (360) 385–7538; *e-mail: www.glen.m@aptalaska.com.*

i. *FERC Contact:* Any questions on this notice should be addressed to Henry Ecton, (202) 502–8768, or *E-mail address: henry.ecton@ferc.gov.*

j. *Deadline for filing comments, protests, and/or motions:* December 05, 2008.

All documents (original and eight copies) should be filed with: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and/or interventions may be filed electronically via the Internet in lieu of paper. Any questions, please contact the Secretary's Office. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Please include the docket number (DI09–2–000) on any comments, protests, and/or motions filed.

k. *Description of Project:* The proposed Connelly Lake Hydropower Project will include: (1) A 48-foot-high, 100-foot-wide rock-filled dam; (2) a lake with a storage capacity of 4,700 acre-feet; (3) a 6,188-foot-long, 30-inch-diameter penstock; (4) a 40-foot-wide, 60-foot-long metal powerhouse containing one or two turbines, with an installed capacity of 6,200 kW; (5) a tailrace emptying into the Chilkoot River; and (6) appurtenant facilities. The proposed project will not be connected to an interstate grid, and will not occupy any tribal or federal lands.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link, select ''Docket No.'' and follow the instructions. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3372, or TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210,.211,.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a

party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTESTS'', AND/OR ''MOTIONS TO INTERVENE'', as applicable, and the Docket Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26784 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–13296–000]

BPUS Generation Development LLC; Notice of Application for Preliminary Permit Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

November 4, 2008.

On October 2, 2008, BPUS Generation Development LLC filed an application, pursuant to section 4(f) of the Federal Power Act (FPA), to study the proposed Banks Lake Pumped Storage Project. The proposed project would be located in Grant and Douglas Counties, Washington. The project facilities would be located on federal lands administered by the U.S. Bureau of Reclamation (USBR) and the U.S. Bureau of Land Management (BLM), and state lands administered by the Washington Department of Fish and Wildlife. In addition, there are two existing dams associated with the lower reservoir of Banks Lake, and both dams are federally owned and operated by the USBR.

The proposed project, using the existing USBR's Banks Lake as the lower reservoir, would consist of: (1) A new lake as the upper reservoir, (2) a new underground powerhouse containing four pump/turbine-generator units with a combined capacity of 1,040 megawatts (MW), (3) new upper and lower intake structures, power tunnel, and tailrace, (4) a new 2.4-mile-long, 500-kilovolt transmission line, and (5) appurtenant facilities. The proposed project would have an average annual generation of 2,978 gigawatt-hours (GWh).

Applicant Contact: Mr. Jeffrey M. Auser, P.E., BPUS Generation Development LLC, 225 Greenfield Parkway, Suite 201, Liverpool, NY 13088, (315) 413–2821.

FERC Contact: Jake Tung, (202) 502–8757.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the ''eLibrary'' link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13296) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26781 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 459–238]

Ameren/UE; Notice of Availability of Environmental Assessment

November 4, 2008.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47879) the Office of Energy Projects has prepared an environmental assessment (EA) for an application filed by Ameren/UE (licensee) on September 10, 2008, requesting Commission approval to permit Utley Development Company, LLC, to construct one new multi-slip boat dock at the Summer Hill development. The project would be located near mile marker 31.2+5.4 of in Barnes Hollow Cove of the Lake of the Ozarks in Camden County, Missouri. The dock would have a total of 14 boat slips, with 12 slips 32 feet long and 12 feet wide and 2 slips 32 feet long and 10 feet wide and would include a central walkway 4 feet wide. No fuel-dispensing and sewage-pumping facilities or dredging are proposed.

The EA evaluates the environmental impacts that would result from approving the licensee's proposal. The EA finds that approval of the application would not constitute a major federal action significantly affecting the quality of the human environment.

The EA is attached to a Commission order titled ''Order Modifying and Approving Non-Project Use of Project Lands and Waters'' which was issued October 31, 2008, and is available for review and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426. The EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number (P–459) excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3372, or for TTY, (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26782 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF08–21–000]

Transcontinental Gas Pipe Line Corporation; Notice of Intent To Prepare an Environmental Assessment for the Proposed 85 North Expansion Project Request for Comments on Environmental Issues and Notice of Public Meetings and Public Site Visits

November 4, 2008.

The Federal Energy Regulatory Commission (FERC or Commission) is in the process of preparing an environmental assessment (EA) on the environmental impacts of the 85 North Expansion Project (85 North Project) involving the construction and operation of new underground natural gas pipeline looping [1] and new and modified compressor stations proposed by Transcontinental Gas Pipe Line Corporation (Transco). The 85 North Project is under review in Docket No. PF08–21–000.

This Notice of Intent (NOI) explains the scoping process that will be used to gather input from the public and interested agencies on the Project. Your input will help determine which issues will be evaluated in the EA. Please note that the scoping period for this Project will close on December 5, 2008.

Comments on the Project may be submitted in written form or verbally. In lieu of, or in addition, to sending written comments, we also invite you to attend the public scoping meetings and public site visits that have been scheduled in the Project area during the week of November 17, 2008. Details on how to submit comments and additional details of the public scoping meetings are provided in the Public Participation section of this notice.

Although a formal application has not been filed, the FERC has already initiated its NEPA review under its pre-filing process. A pre-filing docket number has been assigned to the 85 North Project (PF08–21–000). The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before an application is filed with the FERC.

This NOI is being sent to federal, state, and local government agencies; elected officials; affected landowners; environmental and public interest groups; Indian tribes and regional Native American organizations; commentors and other interested parties; and local libraries and newspapers. We [2] encourage government representatives to notify their constituents of this proposed Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a Transco representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. Transco would seek to negotiate a mutually acceptable agreement. However, if the Project is approved by the FERC, that approval conveys with it the right of federal eminent domain. Therefore, if easement negotiations fail to produce an agreement, and the Project is ultimately approved by the FERC, Transco could initiate condemnation proceedings in accordance with federal law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility on My Land? What Do I Need To Know?'' is available for viewing on the FERC Internet Web site (*http://www.ferc.gov/for-citizens/citizen-guides.asp*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in FERC's proceedings.

Summary of the Proposed Project

Transco has proposed to construct and operate an expansion of Transco's existing Main Line and associated structures with a maximum delivery capacity of 308,500 dekatherms per day. As shown in Appendix 1,[3] the 85 North Project would be located in portions of Mississippi, Alabama, Georgia, South Carolina and North Carolina. Transco has proposed: Approximately 22 miles of 42-inch-diameter pipeline in 3 pipeline loop segments; 1 new Compressor Station; and modifications to 8 other compressor stations on the Transco Mainline.

Location maps depicting the proposed facilities are attached to this NOI as Appendix 1.

Specifically, Transco proposes the following primary components for the 85 North Project:

- 22 miles of 42-inch diameter underground natural gas pipeline consisting of four segments:
  - ➢ Coosa Loop: 4.39 miles of pipeline loop adjacent to Transco's Main line D in Coosa County, Alabama;
  - ➢ Cowpens Loop: 9.39 miles of pipeline loop adjacent to Transco's Main Line C in Spartanburg and Cherokee Counties, South Carolina; and
  - ➢ Iredell Loop: 8.24 miles of loop adjacent to Transco's Main Line C in Iredell and Rowan Counties, North Carolina.
- Construction and operation of the new 20,500 horsepower (hp) Compressor Station 135 in Anderson County, South Carolina;
- Installation of gas cooling facilities at Compressor Station 80 in Jones County, Mississippi;
- Uprate the existing turbine by 1,430 hp and rewheel two compressors at Compressor Station 90 in Marengo County, Alabama;
- Installation of one 42,000 hp electric motor-driven compressor unit, and abandon 4 existing engine-compressor units for a net increase of 16,000 hp at Compressor Station 100 in Chilton County, Alabama;
- Installation of 20,500 hp turbine-compressor unit at Compressor Station 110 in Randolph County, Alabama;
- Uprate the existing electric motor by 3,025 hp at Compressor Station 115 in Coweta County, Georgia;
- Uprate 2 turbines, and replace compressors at Compressor Station 125 in Walton County, Georgia;
- Install additional gas cooling facilities and modify valves at Compressor Station 150 in Iredell County, North Carolina;
- Minor compressor modifications at Station 155 in Davidson County, North Carolina.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission staff requests public comments on the scope of the issues to address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their

[1] A pipeline loop is a segment of pipeline immediately adjacent to an existing pipeline.

[2] ''We'', ''us'', and ''our'' refer to the environmental staff of the Office of Energy Projects (OEP).

[3] The appendices referenced in this notice are not printed in the **Federal Register**, but they are being provided to all those who receive this notice in the mail. Copies of the NOI can be obtained from the Commission's Web site at the ''eLibrary'' link, from the Commission's Public Reference Room, or by calling (202) 502–8371. For instructions on connecting to eLibrary, refer to the end of this notice.

constituents of this proposed action and encourage them to comment on their areas of concern.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils.
- Water resources.
- Aquatic resources.
- Vegetation and wildlife.
- Threatened and endangered species.
- Land use, recreation, and visual resources.
- Cultural resources.
- Socioeconomics.
- Air quality and noise.
- Reliability and safety.
- Cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the Public Participation section.

Currently Identified Environmental Issues

We have already identified issues that we think deserve attention based on our previous experience with similar projects in the region. This preliminary list of issues, which is presented below, may be revised based on your comments and our continuing analyses specific to the 85 North Project.

- Potential for disturbance to residents along pipeline construction route, including noise, and aesthetics;
- Potential impacts of the pipeline on waterbodies and wetlands, including issues of erosion control;
- Potential air quality impacts due to increased emissions from compressor stations; and
- Potential noise and vibration impacts from compressor stations.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the 85 North Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send in your comments so that they will be received in Washington, DC on or before December 5, 2008.

Comments on the proposed Project can be submitted to the FERC in written form or verbally at the public scoping meetings. For your convenience, there are three methods which you can use to submit your written comments to the Commission. In all instances please reference the Project docket number (PF08–21–000) with your submission. The three methods are:

(1) You may file your comments electronically by using the Quick Comment feature, which is located on the Commission's Internet Web site at *http://www.ferc.gov* under the link to Documents and Filings. A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's Internet Web site at *http://www.ferc.gov* under the link to Documents and Filings. eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file as your submission. New eFiling users must first create an account by clicking on ''Sign up'' or ''eRegister.'' You will be asked to select the type of filing you are making. A comment on a particular project is considered a ''Comment on a Filing;'' or

(3) You may file your comments via mail to the Commission by sending an original and two copies of your letter to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.

Label one copy of the comments for the attention of Gas Branch 3, PJ–11.3.

The public scoping meetings and public site visits (dates, times, and locations listed below) are designed to provide another opportunity to offer comments on the proposed Project. Interested groups and individuals are encouraged to attend the meetings and to present comments on the environmental issues that they believe should be addressed in the EA. Please note that attendees at the site visit must obtain their own transportation.

A transcript of the scoping meetings will be generated so that your comments can be accurately recorded. There will be no official proceedings of the public site visits. All Scoping Meetings are scheduled to run from 7 to 9 p.m. The schedule for meetings and site visits are as follows:

Date	Location
Tuesday, November 18, Scoping Meeting, 7 to 9 p.m. CST	Best Western Horseshoe Inn, 3146 Highway 280, Alexander City, AL 35010.
Wednesday, November 19, Public Site Visit, 1 p.m. EST	Transco Compressor Station 125, 1001 James Huff Road, Monroe, GA 30656.
Thursday, November 20, Scoping Meeting, 7 to 9 p.m. EST	American Legion Post 28, 94 West Park Drive, Spartanburg, SC 29306.
Friday, November 21, Public Site Visit, 10 a.m. EST	Transco Compressor Station 150, 236 Transco Road, Mooresville, NC 28115.

The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at 202–502–8258 or *efiling@ferc.gov.*

Once Transco formally files its application with the Commission, you may want to become an ''intervenor,'' which is an official party to the proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in a Commission proceeding by filing a request to intervene. Instructions for

becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that you may not request intervenor status at this time. You must wait until a formal application is filed with the Commission.

Environmental Mailing List

An effort is being made to send this notice to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project. This includes all landowners whose property may be used temporarily for project purposes, who have existing easements from the pipeline, or who own homes within distances defined in the Commission's regulations of certain aboveground facilities. By this notice we are also asking governmental agencies, especially those in Appendix 2, to express their interest in becoming cooperating agencies for the preparation of the EA.

If you do not want to send comments at this time but still want to remain on our mailing list, please return the Information Request (Appendix 3). If you do not return the Information Request, you will be taken off the mailing list.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs at 1–866–208–FERC (3372), or on the FERC Internet Web site (*http://www.ferc.gov*) using the ''eLibrary link.'' Click on the eLibrary link, select ''General Search'' and enter the Project docket number, excluding the last three digits (*i.e.*, PF08–21) in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance with eLibrary, the eLibrary helpline can be reached at 1–866–208–3676, TTY (202) 502–8659, or by e-mail at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

In addition, the FERC now offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm.*

Public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26783 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER09–138–000]

FPL Energy Oliver Wind I, Inc.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 4, 2008.

This is a supplemental notice in the above-referenced proceeding of FPL Energy Oliver Wind I, Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest 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). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is November 24, 2008.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–26773 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER09–139–000]

Red Wolf Energy Trading, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

November 4, 2008.

This is a supplemental notice in the above-referenced proceeding of Red Wolf Energy Trading, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest 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). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is November 24, 2008.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic

service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.

Deputy Secretary.

[FR Doc. E8–26772 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[RT01–99–000, RT01–99–001, RT01–99–002 and RT01–99–003; RT01–86–000, RT01–86–001 and RT01–86–002, RT01–95–000, RT01–95–001, and RT01–95–002, RT01–2–000, RT01–2–001, RT01–2–002, and RT01–2–003, RT01–98–000, RT02–3–000]

Regional Transmission Organizations, Bangor Hydro-Electric Company, et al.; New York Independent System Operator, Inc.; et al.; PJM Interconnection, L.L.C., et al.; PJM Interconnection, L.L.C.; ISO New England, Inc.; New York Independent System Operator, Inc.; NOTICE

November 4, 2008.

Take notice that PJM Interconnection, L.L.C., New York Independent System Operator, Inc. and ISO New England, Inc. have posted on their Internet Web sites information updating their progress on the resolution of RTO seams.

Any person desiring to file comments on this information 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). All such comments should be filed on or before the comment date. 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. The Commission strongly encourages electronic filings.

Comment Date: November 24, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26780 Filed 11–10–08; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

EPA–HQ–OPP–2007–0588;FRL–8388–5]

Acrolein, d-Phenothrin, and Sulfometuron Methyl, Reregistration Eligibility Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's Reregistration Eligibility Decisions (REDs) for the pesticides acrolein, d-phenothrin, and sulfometuron methyl, and opens a public comment period on this document. The Agency's risk assessments and other related documents also are available in the acrolein, d-phenothrin, and sulfometuron methyl Dockets. Acrolein is a biocide used as a herbicide in irrigation canals and as an antimicrobial agent for drilling muds in the petroleum industry. d-Phenothrin is a synthetic pyrethroid with indoor uses in foggers, carpet powders, crack and crevice treatments, and pet care products and outdoor uses as a mosquito adulticide. Sulfometuron methyl is a non-selective sulfonylurea herbicide primarily used for weed control in forestry and vegetative management. Neither acrolein, d-phenothrin, or sulfometuron methyl have any food uses. EPA has reviewed acrolein, d-phenothrin, and sulfometuron methyl through the public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

DATES: Comments must be received on or before January 12, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) numbers EPA–HQ–OPP–2007–0588 (Acrolein); EPA–HQ–OPP–2008–0140 (d-Phenothrin); EPA–HQ–OPP–2008–0129 (Sulfometuron Methyl), by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID numbers EPA–HQ–OPP–2007–0588 (Acrolein); EPA–HQ–OPP–2008–0140 (d-Phenothrin); EPA–HQ–OPP–2008–0129 (Sulfometuron Methyl). EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form

of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although,listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Laura Parsons, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5776; fax number: (703) 308–7042; e-mail address: *parsons.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to: When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

Under section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is reevaluating existing pesticides to ensure that they meet current scientific and regulatory standards. EPA has completed REDs for the pesticides, acrolein, d-phenothrin, and sulfometuron methyl under section 4(g)(2)(A) of FIFRA. Acrolein is a biocide used as a herbicide in irrigation canals and as an antimicrobial agent for drilling muds in the petroleum industry. d-Phenothrin is a pyrethroid with indoor uses of foggers, carpet powders, crack and crevice treatments, and pet care products and outdoor uses as a mosquito adulticide. Sulfometuron methyl is a non-selective sulfonylurea herbicide primarily used for weed control in forestry and vegetative management. Neither acrolein, sulfometuron methyl, or d-phenothrin have any food uses. EPA has determined that the database to support reregistration is substantially complete and that products containing acrolein, d-phenothrin, and sulfometuron methyl are eligible for reregistration, provided the risks are mitigated either in the manner described in the RED or by another means that achieves equivalent risk reduction. Upon submission of any required product specific data under section 4(g)(2)(B) of FIFRA and any necessary changes to the registration and labeling (either to address concerns identified in the RED or as a result of product specific data), EPA will make a final reregistration decision under section 4(g)(2)(C) of FIFRA for products containing acrolein, d-phenothrin, and sulfometuron methyl.

TABLE 1.—REREGISTRATION ELIGIBILITY DECISION DOCKETS OPENING

Reregistration Case Name and Number	Docket ID Number	Chemical Review manager, Telephone Number, E-mail Address
Acrolein, 2005	EPA—HQ–OPP–2007–0588	Laura Parsons (703) 305–5776, *parsons.laura@epa.gov*
d-Phenothrin, 0426	EPA–HQ–OPP–2008–0140	Jennifer Howenstine, (703) 305–0741, *howenstine.jennifer@epa.gov*
Sulfometuron Methyl, 3136	EPA–HQ–OPP–2008–0129	Rusty Wasem, (703) 305–6979, *wasem.russell@epa.gov*

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004, (69 FR 26819) (FRL–7357–9) explains that in conducting these programs, EPA is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. Due to their uses, risks, and other factors, d-phenothrin and sulfometuron methyl were reviewed through the modified 4–Phase public participation process. Acrolein was reviewed through the 6–phase process. Through this process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for acrolein, d-phenothrin, and sulfometuron methyl.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA, as amended, directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products and either reregistering products or taking other ''appropriate regulatory action.''

List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 31, 2008.

Steven Bradbury,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E8–26718 Filed 11–10–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2008–0692; FRL–8740–1]

RIN 2040–ZA02

Drinking Water: Preliminary Regulatory Determination on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Reopening of public comment period.

SUMMARY: EPA announced on October 10, 2008, its preliminary regulatory determination that a national primary drinking water regulation for perchlorate would not present ''a meaningful opportunity for health risk reduction for persons served by public water systems.'' In response to requests from several stakeholders, this action reopens the public comment period for an additional 15 days.

DATES: EPA must receive your comments on or before November 28, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2008–0692, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* Water Docket, EPA Docket Center (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2008–0692. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Eric Burneson, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564–5250 or e-mail *burneson.eric@epa.gov*. For general information contact the EPA Safe Drinking Water Hotline at (800) 426–4791 or e-mail: *hotline-sdwa@epa.gov*.

SUPPLEMENTARY INFORMATION: The Safe Drinking Water Act requires EPA to make determinations every five years of whether to regulate at least five contaminants on the Contaminant Candidate List (CCL). EPA included perchlorate on the first and second CCLs that were published in the **Federal Register** on March 2, 1998 (63 FR 10273) and February 24, 2005 (70 FR 9071). Most recently, EPA presented final regulatory determinations regarding 11 contaminants on the second CCL in a notice published in the **Federal Register** on July 30, 2008. On October 10, 2008 (73 FR 60262), EPA presented supporting rationale and requested public comment on its preliminary determination not to regulate perchlorate (please note that EPA has issued a new RIN number for this action which is 2040–AF02). EPA will make a final regulatory determination for perchlorate after considering comments and information provided in the comment period following this notice. The original comment deadline was November 10, 2008. Several stakeholders have requested a reopening to the comment period in order to evaluate EPA's findings, review the scientific literature and prepare comments. This action reopens the comment period for 15 days.

Dated: November 6, 2008.

Benjamin H. Grumbles,

Assistant Administrator, Office of Water.

[FR Doc. E8–26945 Filed 11–10–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8739–8]

Science Advisory Board Staff Office; Clean Air Scientific Advisory Committee (CASAC); Notification of a Public Advisory Committee Teleconference of the CASAC Oxides of Nitrogen Primary NAAQS Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee's (CASAC) Oxides of Nitrogen Primary NAAQS Review Panel (Panel) to review EPA's completed *Risk and Exposure Assessment to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard* and to provide advice for EPA to consider as it develops its Advance Notice for Proposed Rulemaking for nitrogen dioxide.

DATES: The teleconference will be held on December 5, 2008 from 1 p.m. to 3 p.m. (Eastern Daylight Time).

Location: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the call-in number and access code to participate in the teleconference may contact Dr. Angela Nugent, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343–9981; fax (202) 233–0643; or e-mail at *nugent.angela@epa.gov*. General information concerning the CASAC and the CASAC documents cited below can be found on the EPA Web site at *http://www.epa.gov/casac*.

SUPPLEMENTARY INFORMATION:

Background: The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. CASAC provides advice, information, and recommendations on the scientific and technical aspects of air quality criteria and national ambient air quality standards (NAAQS) under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six ''criteria'' air pollutants, including oxides of nitrogen (NO_X). EPA is in the process of reviewing the primary NAAQS for nitrogen dioxide (NO_2), an indicator for NO_X. Primary standards set limits to protect public health, including the health of ''sensitive'' populations such as asthmatics, children, and the elderly.

As part of its scientific advice to support EPA's review of the primary NAAQS for nitrogen dioxide (NO_2), CASAC met on September 9–10, 2008 to conduct a peer review of the *Risk and Exposure Assessment to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard: Second Draft* (73 FR 43444–43445). At that time, EPA had not completed chapter eight of the draft assessment entitled ''Exposure and Health Risk Characterization.'' CASAC also held a public teleconference on October 22, 2008 to conduct a peer review of the draft chapter 8 (73 FR 55074–55075).

The public may access completed CASAC advisory reports related to the primary NO_2 NAAQS, including the CASAC reports on the *Risk and Exposure Assessment to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard: Second Draft*, on the EPA Web site at *http://yosemite.epa.gov/sab/sabproduct.nsf/WebReportsbyTopicCASAC!OpenView*.

EPA now plans that the final document will include an additional chapter (chapter 10) that considers the scientific evidence and exposure-risk-based information specifically as it relates to the current and potential alternative standards. At the December 5, 2008 teleconference, the CASAC will review EPA's completed *Risk and Exposure Assessment* and provide advice for EPA to consider as it develops its Advance Notice for Proposed Rulemaking for nitrogen dioxide.

Technical Contact: Any questions concerning *Risk and Exposure Assessment to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard* should be directed to Dr. Scott Jenkins, OAR (by telephone (919) 541–1167 or e-mail *jenkins.scott@epa.gov*.

Availability of Meeting Materials: EPA's *Risk and Exposure Assessment to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard* will be accessible via the Agency's Office of Air Quality Planning and Standards Web site at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html* on or about November 21, 2008. Agendas and materials supporting the teleconference will be placed on the EPA Web site before the meeting on the CASAC meeting page, accessible through the calendar link on the blue navigation bar at *http://www.epa.gov/casac*.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the CASAC Panel to consider during the advisory process. *Oral Statements:* Interested members of the public may submit relevant written or oral information for the SAB Panel to consider during the advisory process. *Oral Statements:* In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes per speaker, with no more than a total of 30 minutes for all speakers. Interested parties should contact Dr. Angela Nugent, DFO, in writing (preferably via e-mail) by December 1, 2008 at the contact information noted above to be placed on the public speaker list for this meeting. *Written Statements:* Written statements for the public meeting should be received by Dr. Angela Nugent at the contact information above by December 1, 2008, so that the information may be made available to the Panel for their consideration prior to the teleconference. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature (optional), and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format).

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Nugent at the phone number or e-mail address noted above, preferably at least ten days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: November 5, 2008.

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E8–26846 Filed 11–10–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8739–9]

Proposed Issuance of a General NPDES Permit (GP) for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country in the State of Washington (Permit Number WAG–13–0000)

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of a draft general NPDES permit.

SUMMARY: Some of the federal and tribal aquaculture facilities proposed to be covered under this general permit have

expired individual NPDES permits; others have never been issued such a permit. The Director, Office of Water and Watersheds, EPA Region 10, proposes to issue a general permit to cover Federal aquaculture facilities and aquaculture facilities in Indian country, as defined in 18 U.S.C. 1151, within the State of Washington.

DATES: Comments must be received or postmarked by December 29, 2008. Persons wishing to request a public hearing should submit their written request by November 28, 2008, stating the nature of the issues to be raised as well as the requester's name, address and telephone number to Sharon Wilson at the address below.

ADDRESSES:

Public Comment: All comments on the proposed General Permit and requests for public hearing must be sent to Sharon Wilson, USEPA Region 10; 1200 Sixth Avenue, Suite 900, OWW–130, Seattle, Washington 98101–3140 or by e-mail to *wilson.sharon@epa.gov.*

Public Meeting: EPA will hold a public meeting to provide an overview of the permit and to answer questions.

Location: U.S Environmental Protection Agency.

Address: 1200 Sixth Avenue, 12th floor, Seattle, WA.

Date: Wednesday, December 17, 2008.

Permit Overview: 1–1:30 p.m.

Questions & Answers: 1:30 to 3 p.m. or until done.

FOR FURTHER INFORMATION CONTACT: Sharon Wilson, 206–553–0325, or *wilson.sharon@epa.gov* for technical information. Copies of the draft general permit and fact sheet are also available upon request from Audrey Washington at 206–553–0523 or *washington.audrey@epa.gov*.

SUPPLEMENTARY INFORMATION:

Fact Sheet: A fact sheet has been prepared which sets forth the principal factual, legal, policy, and scientific information considered in the development of the draft general permit. Copies of the draft permit and fact sheet are available for public review at:

U.S. EPA Region 10, NPDES Permits Unit, OWW–130, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101–3140;

Northwest Indian Fisheries Commission, 6730 Martin Way East, Olympia, WA 98516.

The general permit and fact sheet may also be downloaded at *http://yosemite.epa.gov/r10/water.nsf/NPDES+Permits/DraftPermitsORWA.* The complete administrative record for the draft permit is available for public review at the EPA Region 10 office at the address listed above.

Public Meeting: Written comments receive as much consideration as oral comments at a public hearing. Persons wishing to request a public hearing should submit their written request by the date designated in the **DATES** section above, stating the nature of the issues to be raised as well as the requester's name, address and telephone number to Sharon Wilson at the address above. If a public hearing is scheduled, notice will be published in the **Federal Register**. Notice will also be posted on the Region 10 Web site and will be mailed to all interested persons receiving notice of availability of the draft permit.

Other Legal Requirements

A. Endangered Species Act

EPA has determined that issuance of the General Permit is not likely to adversely affect threatened or endangered fish, marine mammals, or birds, designated critical habitat, or essential fish habitat. EPA has also determined that issuance of the permit will have no effect on threatened or endangered marine reptiles, terrestrial animals, or invertebrates.

B. Executive Order 12866

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

C. Paperwork Reduction Act

The information collection requirements of this permit were previously approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and assigned OMB control numbers 2040–0086 (NPDES permit application) and 2040–0004 (discharge monitoring reports).

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires that EPA prepare a regulatory flexibility analysis for rules subject to the requirements of 5 U.S.C. 553(b) that have a significant impact on a substantial number of small entities. However, general NPDES permits are not ''rules'' subject to the requirements of 5 U.S.C. 553(b) and are therefore not subject to the RFA.

E. Unfunded Mandates Reform Act

Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104–4, generally requires Federal agencies to assess the effects of their ''regulatory actions'' (defined to be the same as ''rules'' subject to the RFA) on tribal, state, and local governments and the private sector. However, general NPDES permits are not ''rules'' subject to the requirements of 5 U.S.C. 553(b) and are therefore not subject to the RFA or the UMRA.

Dated: November 3, 2008.

Michael F. Gearheard,

Director, Office of Water & Watersheds, Region 10.

[FR Doc. E8–26865 Filed 11–10–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008–0046; FRL–8386–8]

Notice of Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the Agency's receipt of several initial filing of pesticide petitions proposing the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities

DATES: Comments must be received on or before December 12, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID number and the pesticide petition number of interest as shown in the body of this document. EPA's policy is that all comments received will be included in the docket without change

and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: A contact person, with telephone number and e-mail address, is listed at the end of each pesticide petition summary. You may also reach each contact person by mail at Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 at the end of the pesticide petition summary of interest.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this notice, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is

available on-line at *http://www.regulations.gov*.

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

A. New Exemption from a Tolerance

1. *PP 8F7327*. (EPA–HQ–OPP–2008–0749). Isagro, S.p.A., Via Caldera 21, fabbricato D, la 3, Milano, Italy, proposes to establish an exemption from the requirement of a tolerance for residues of the fungicide, *Trichoderma gamsii* (strain ICC 080), in or on all food/feed commodities. Because this petition is a request for an exemption from the requirement of a tolerance without numerical limitations, no analytical method is required. Contact: Susanne Cerrelli, (703) 308–8077, *cerrelli.susanne@epa.gov*.

2. *PP 8F7326*. (EPA–HQ–OPP–2008–0750). Isagro, S.p.A., Via Caldera 21, fabbricato D, la 3, Milano, Italy, proposes to establish an exemption from the requirement of a tolerance for residues of the fungicide, *Trichoderma asperellum* (strain ICC 012), in or on all food/feed commodities. Because this petition is a request for an exemption from the requirement of a tolerance without numerical limitations, no analytical method is required. Contact: Susanne Cerrelli, (703) 308–8077, *cerrelli.susanne@epa.gov*.

B. Amendment to an Existing Tolerance

3. *PP 8F7376*. (EPA–HQ–OPP–2008–0606). Luxembourg-Pamol, Inc., 5100 Poplar Ave., Suite 2700, Memphis, TN 38137, proposes to amend the tolerance in 40 CFR 180.1210 for residues of the fungicide, phosphorous acid and its ammonium, sodium, and potassium salts, in or on citrus at 35,600 parts per million (ppm). Contact: John Fournier, (703) 308–0169, *fournier.john@epa.gov*.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 27, 2008.

Janet L. Andersen,

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

[FR Doc. E8–26479 Filed 11–10–08; 8:45 am]

Billing Code 6560–50–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Equal Employment Opportunity Commission.

DATE AND TIME: Thursday, November 20, 2008, 9:30 A.M. Eastern Time.

PLACE: Clarence M. Mitchell, Jr. Conference Room on the Ninth Floor of the EEOC Office Building, 1801 ''L'' Street, NW., Washington, DC 20507.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Open Session:

1. Announcement of Notation Votes, and
2. Employment Discrimination Against Individuals with Arrest and Conviction Records—Invited Experts.

Note: In accordance with the Sunshine Act, the meeting will be open to public observation of the Commission's deliberations and voting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTY) at any time for information on these meetings. The EEOC provides sign language interpretation at Commission meetings for the hearing impaired. Requests for other reasonable accommodations may be made by using the voice and TTY numbers listed above.

CONTACT PERSON FOR MORE INFORMATION: Stephen Llewellyn, Executive Officer on (202) 663–4070.

Dated: November 6, 2008.

This Notice Issued November 6, 2008.

Stephen Llewellyn,

Executive Officer, Executive Secretariat.

[FR Doc. E8–26968 Filed 11–7–08; 4:15 pm]

BILLING CODE 6570–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:03 a.m. on Thursday, November 6, 2008, the Board of Directors of the Federal Deposit Insurance Corporation met in open session to consider the following matter:

resolution re: Extension of Comment Period for Proposed Rules on the Risk Based Assessment System.

In calling the meeting, the Board determined, on motion of Director Thomas J. Curry (Appointive), seconded by Vice Chairman Martin J. Gruenberg, concurred in by Director John M. Reich (Office of Thrift Supervision), Julie L. Williams, acting in the place and stead of Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matter on less than seven days' notice to the public; and that no earlier notice of the meeting was practicable.

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: November 6, 2008.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. E8–26829 Filed 11–10–08; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:09 a.m. on Thursday, November 6, 2008, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Director Thomas J. Curry (Appointive), concurred in by Director John M. Reich (Director, Office of Thrift Supervision), Julie L. Williams, acting in the place and stead of Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii) and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: November 6, 2008.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. E8–26830 Filed 11–10–08; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 5, 2008.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. Mt. Sterling Bancorp, Inc., Mt. Sterling, Illinois, to acquire 100 percent of the voting shares of Timewell State Bank, Timewell, Illinois.

B. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Big Country Bancshares, Inc., Abilene, Texas, to become a bank holding company by acquiring 100 percent of the voting shares of Citizens Bank, N.A., Abilene, Texas.

Board of Governors of the Federal Reserve System, November 6, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–26808 Filed 11–10–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Coordinating Center for Infectious Diseases (CCID)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates:

9 a.m.–5 p.m., December 4, 2008.

8:30 a.m.–3:30 p.m., December 5, 2008.

Place: CDC, Global Conference Center, Building 19, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

December 4, 2008—Building 19 (Work Groups meet).

December 5, 2008—Auditorium B3 (Full Board meets).

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, CCID, provides advice and guidance to the Director, CDC, and Director, CCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters to be Discussed: Agenda items will include:

1. *Breakout Group Discussions:* Vaccine Trust and Vaccine in Healthcare Workers (National Center for Preparedness, Detection, and Control of Infectious Diseases and National Center for Immunization and Respiratory Diseases). Discussion will be how reports, statements and recommendations of our established advisory committees (Advisory Council for the Elimination of Tuberculosis, CDC/HRSA Advisory Committee) can be presented to the Work Group and full committee most efficiently and effectively (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, (NCHHSTP)). Program Collaboration and Service Integration (NCHHSTP) International Activities (National Center for Zoonotic, Vector-Borne, and Enteric Diseases, (NCZVED)). Peer Reviews and Planning and New Technology (NCZVED).

2. Antimicrobial Resistance (Full Board).

3. Budget and CCID/Office of the Director Updates (Full Board).

Other agenda items include announcements, introductions, and follow-up on actions recommended by the board, directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Harriette Lynch, Office of the Director, CCID, CDC, Mailstop E–77, 1600 Clifton Road, NE., Atlanta, Georgia 30333, *Telephone:* (404)498–2726, *e-mail: hlynch@cdc.gov.*

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–26795 Filed 11–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Marketing (BSC, NCHM)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting of the aforementioned committee:

Times and Dates: 9 a.m.–4:30 p.m., December 8, 2008. 9 a.m.–3 p.m., December 9, 2008.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 21, Auditorium A (Room 1204A), Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people.

Purpose: The Secretary, Department of Health and Human Services (HHS), and, by delegation, the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act (PHSA), as amended to: develop and implement disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States. Under these and additional PHSA and other authorities, CDC acts by identifying and defining preventable health problems; maintaining active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution; conducting operational research aimed at developing and testing effective disease prevention, control, and health

promotion programs; administering a national occupational safety and health program; controlling the introduction and spread of infectious diseases; and providing consultation and assistance to other nations and international agencies to assist in improving their disease prevention and control, environmental health, and health promotion activities. CDC carries out these functions through a number of Coordinating Centers/Offices and National Centers and Institutes with expertise and responsibilities in specific areas.

Matters to be Discussed: The agenda will include discussions on program activities, including scientific programs, that will assist in consolidating and refining NCHM vision, mission, goals, organizational structure and expanding and implementing its science for the National Center for Health Marketing; and discussions related to the National Center's role in preparedness, response and recovery with regards to an outbreak of pandemic influenza

Agenda items are tentative and subject to change.

Contact Person for More Information: Dionne R. Mason, Committee Management Specialist, NCHM, 1600 Clifton Road, Mail Stop E–21, Atlanta, Georgia 30333, *Telephone:* (404) 498–2314, Fax (404) 498–2221. The deadline for notification of attendance is November 20, 2008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E8–26803 Filed 11–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting for the aforementioned committee:

Times and Date: 1 p.m.–2:30 p.m., December 8, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the reporting and voting of the peer reviews conducted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcements: (1) RFA–CD–08–001, ''Elimination of Health Disparities Through Translation Research (R18)'' and (2) RFA–CE–09–001, ''Grants for the Injury Control Research Centers''. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Rick Waxweiler, PhD, Director, Extramural Research Program Office, NCIPC and Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., Mail Stop F–62, Atlanta, Georgia 30341, *Telephone:* (770) 488–4850.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–26801 Filed 11–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0345]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 12, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback'' (OMB Control Number 0910–0116—Extension)

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic (FD&C) Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is

defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351(a)), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (CGMP) and related regulations.

The CGMP regulations (part 606) (21 CFR part 606) and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in notifying donors is to prevent the transmission of communicable disease. For example, the ''lookback'' requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to users of blood and blood components and appropriate notification of recipients of transfusion who are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donor testing, donor notification, and ''Lookback'' regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventive and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

Under the reporting requirements, § 606.170(b), in brief, requires that facilities notify FDA's Center for Biologics Evaluation and Research (CBER), as soon as possible after confirming a complication of blood collection or transfusion to be fatal. The collecting facility is to report donor fatalities, and the compatibility testing facility is to report recipient fatalities. The regulation also requires the reporting facility to submit a written report of the investigation within 7 days after the fatality. In fiscal years 2006 and 2007, FDA received, on average, 100 of these reports.

Section 610.40(c)(1)(ii) (21 CFR 610.40(c)(1)(ii)), in brief, requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121 and with a label entitled ''INTENDED RECIPIENT INFORMATION LABEL'' containing the name and identifying information of the recipient.

Section 610.40(g)(2) (21 CFR 610.40(g)(2)) requires an establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use prior to completion of testing for evidence of infection due to certain communicable disease agents.

Section 610.40(h)(2)(ii)(A) (21 CFR 610.40(h)(2)(ii)(A)), in brief, requires an establishment to obtain written approval from FDA to use or ship human blood or blood components found to be reactive by a screening test for evidence of certain communicable disease agent(s) or collected from a donor with a record of a reactive screening test. Furthermore, § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D) (21 CFR 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)), in brief, requires an establishment to label certain reactive human blood and blood components with the appropriate screening test results, and, if they are intended for further manufacturing use into injectable products, include a statement on the label indicating the exempted use specifically approved by FDA. Finally, § 610.40(h)(2)(vi) (21 CFR 610.40(h)(2)(vi)) requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results.

Section 610.42(a) (21 CFR 610.42(a)) requires a warning statement ''indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified communicable disease agent(s)'' in the labeling for medical devices containing human blood or a blood component found to be reactive by a screening test for evidence of infection due to a communicable disease agent(s) or syphilis.

In brief, §§ 610.46 and 610.47 (21 CFR 610.46 and 610.47) require blood collecting establishments to establish, maintain, and follow an appropriate system for performing HIV and HCV prospective ''lookback'' when: (1) A donor tests reactive for evidence of HIV or HCV infection or (2) the collecting establishment becomes aware of other reliable test results or information indicating evidence of HIV or HCV infection (''prospective lookback''). (See §§ 610.46(a)(1) and 610.47(a)(1).) The requirement for ''an appropriate system'' requires the collecting establishment to design standard operating procedures (SOPs) to identify and quarantine all blood and blood components previously collected from a donor who later tests reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection. Within 3 calendar days of the donor testing reactive by an HIV or HCV screening test or the collecting establishment becoming aware of other reliable test results or information, the collecting establishment must, among other things, notify consignees to quarantine all identified previously collected in-date blood and blood components (§§ 610.46(a)(1)(ii)(B) and 610.47(a)(1)(ii)(B)) and, within 45 days, notify the consignees of supplemental test results, or the results of a reactive screening test if there is no available supplemental test that is approved for such use by FDA (§§ 610.46(a)(3) and 610.47(a)(3)).

Consignees also must establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when notified by the collecting establishment that they have received blood and blood components previously collected from donors who later tested reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection in a donor (§§ 610.46(b) and 610.47(b)). This provision for a system requires the consignee to establish SOPs for, among other things, notifying transfusion recipients of blood and blood components, or the recipient's physician of record or legal representative, when such action is indicated by the results of the supplemental (additional, more specific) tests or a reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or an investigational device exemption (IDE), is exempted for such use by FDA. The consignee must make reasonable attempts to perform the notification within 12 weeks of receipt

of the supplemental test result or receipt of a reactive screening test result when there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA (§§ 610.46(b)(3) and 610.47(b)(3)).

Section 630.6(a) (21 CFR 630.6(a)) requires an establishment to make reasonable attempts to notify any donor who has been deferred as required by § 610.41 (21 CFR 610.41), or who has been determined not to be eligible as a donor. Section 630.6(d)(1) requires an establishment to provide certain information to the referring physician of an autologous donor who is deferred based on the results of tests as described in § 610.41.

Under the recordkeeping requirements, § 606.100(b), in brief, requires that written SOPs be maintained for all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components used for transfusion and further manufacturing purposes. Section 606.100(c) requires the review of all records pertinent to the lot or unit of blood prior to release or distribution. Any unexplained discrepancy or the failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded.

In brief, § 606.110(a) provides that the use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for that specific product if, among other things, the physician certifies in writing that the donor's health permits plateletpheresis or leukapheresis. Section 606.110(b) requires establishments to request prior approval from CBER for plasmapheresis of donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are approved under OMB control number 0910–0338 and, therefore, are not reflected in tables 1 and 2 of this document.

Section 606.151(e) requires that SOPs for compatibility testing include procedures to expedite transfusion in life-threatening emergencies; records of all such incidents must be maintained, including complete documentation justifying the emergency action, which must be signed by a physician.

So that each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components can be clearly traced, § 606.160 requires that legible and indelible contemporaneous records of each such step be made and maintained for no less than 10 years. Section 606.160(b)(1)(viii) requires records of the quarantine, notification, testing and disposition performed under the HIV and HCV ''lookback'' provisions. Furthermore, § 606.160(b)(1)(ix) requires a blood collection establishment to maintain records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup. Section 606.160(b)(1)(xi) requires an establishment to maintain records of notification of the referring physician of a deferred autologous donor, including appropriate followup.

Section 606.165, in brief, requires that distribution and receipt records be maintained to facilitate recalls, if necessary.

Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions arising as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. When an investigation concludes that the product caused the transfusion reaction, copies of all such written reports must be forwarded to and maintained by the manufacturer or collecting facility.

Section 610.40(g)(1) (21 CFR 610.40(g)(1)) requires an establishment to appropriately document a medical emergency for the release of human blood or blood components prior to completion of required testing.

In addition to the CGMP regulations in part 606, there are regulations in part 640 (21 CFR part 640) that require additional standards for certain blood and blood components as follows: Sections 640.3(a)(1), (a)(2), and (f); 640.4(a)(1) and (a)(2); 640.25(b)(4) and (c)(1); 640.27(b); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.66; 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in tables 1 and 2 of this document.

Respondents to this collection of information are licensed and unlicensed blood establishments that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and other transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 81 licensed Source Plasma establishments with multiple locations and approximately 2,000 registered blood collection establishments, for an estimated total of 2,081 establishments. Of these establishments, approximately 696 perform plateletpheresis and leukapheresis. These establishments annually collect approximately 28 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA ''lookback'' procedures. In addition, there are another 4,980 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The following reporting and recordkeeping estimates are based on information provided by industry, CMS, and FDA experience. Based on information received from industry, we estimate that there are approximately 13 million donations of Source Plasma from approximately 2 million donors and approximately 15 million donations of Whole Blood, including approximately 300,000 (2 percent of 15 million) autologous donations, from approximately 8 million donors. Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 150,000 autologous donors.

FDA estimates that approximately 5 percent (12,000) of the 240,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors' testing provisions in § 610.40(c)(1)(ii).

Under § 610.40(g)(2) and (h)(2)(ii)(A), the only product currently shipped prior to completion of testing for evidence of certain communicable disease agents is a licensed product, Source Leukocytes, used in the manufacture of interferon, which requires rapid preparation from blood. Shipments of Source Leukocytes are pre-approved under a biologics license application and each shipment does not have to be reported to the agency. Based on information from CBER's database system, FDA receives less than one application per year from manufacturers of Source Leukocytes. However, for calculation purposes, we are estimating one application annually.

Under § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D), FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood components per month (12 per year)

that would require 2 labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D). According to CBER's database system, there are approximately 40 licensed manufacturers that ship known reactive human blood or blood components.

Based on information we received from industry, we estimate that approximately 18,000 donations: (1) Annually test reactive by a screening test for syphilis, (2) are determined to be biological false positives by additional testing, and (3) are labeled accordingly (§ 610.40(h)(2)(vi)).

Human blood or a blood component with a reactive screening test, as a component of a medical device, is an integral part of the medical device, e.g., a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement that identifies the communicable disease agent. In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, then a warning statement must be affixed to the medical device. To account for this rare occasion under § 610.42(a), we estimate that the warning statement would be necessary no more than once a year.

FDA estimates that approximately 3,500 repeat donors will test reactive on a screening test for HIV. We also estimate that an average of three components was made from each donation. Under § 610.46(a)(1)(ii)(B) and (a)(3), this estimate results in 10,500 (3,500 x 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 10,500 (3,500 x 3) notifications to consignees of subsequent test results. We estimate an average of 10 minutes per notification of consignees.

Moreover, we estimate that § 610.46(b)(3) will require 4,980 consignees to notify transfusion recipients, their legal representatives, or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors x 3) notifications. Under § 610.46(b)(3), we also estimate 1 hour to accommodate the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, we estimate that approximately 7,800 repeat donors per year would test reactive for antibody to HCV. Under § 610.47(a)(1)(ii)(B) and (a)(3), collecting establishments would notify the consignee 2 times for each of the 23,400 (7,800 x 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 46,800 notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,980 consignees would notify approximately 2,050 recipients or their physicians of record annually. Finally, we estimate 1.0 hours to complete notification.

Industry estimates that approximately 13 percent of 10 million potential donors (1.3 million donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 2,000 blood collecting establishments to notify onsite and to explain why the donor is determined not to be suitable for donating. Based on such available information, we estimate that two-thirds (1,333) of the 2,000 blood collecting establishments provided onsite additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, we estimate that only one-third, or 667, approximately, blood collecting establishments would need to provide, under § 630.6(a), additional information and onsite counseling to the estimated 430,000 (one-third of approximately 1.3 million) ineligible donors.

It is estimated that another 4.5 percent of 10 million potential donors (450,000 donors) are deferred annually based on test results. We estimate that currently approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who have reactive test results for HIV, Hepatitis B Virus (HBV), HCV, Human T-Lymphotropic Virus (HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent of the 2,081 establishments (104) collecting 1 percent (4,500) of the deferred donors (450,000) would notify donors under § 630.6(a).

As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.6(d)(1). However, we estimate that approximately 5 percent of the 2,000 blood collection establishments (100) may not notify the referring physicians of the estimated 2 percent of 150,000 autologous donors with the initial reactive test results (3,000) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95 percent of the recordkeepers, which collect 99 percent of the blood supply, have developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(ix), we estimate the total annual records based on the approximately 1.3 million donors determined not to be eligible to donate and each of the estimated 1.75 million (1.3 million + 450,000) donors deferred based on reactive test results for evidence of infection because of communicable disease agents. Under § 606.160(b)(1)(xi), only the 2,000 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 150,000 autologous donors (6,750) will be deferred under § 610.41, which in turn will lead to the notification of their referring physicians.

FDA has concluded that the use of untested or incompletely tested but appropriately documented human blood or blood components in rare medical emergencies should not be prohibited. We estimate the recordkeeping under § 610.40(g)(1) to be minimal with 1 or fewer occurrences per year. The reporting of test results to the consignee in § 610.40(g) does not create a new burden for respondents because it is the usual and customary business practice or procedure to finish the testing and provide the results to the manufacturer responsible for labeling the blood products.

The hours per response and hours per record are based on estimates received from industry or FDA experience with similar recordkeeping or reporting requirements.

In the **Federal Register** of June 24, 2008 (73 FR 35694) (June 2008 document), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one public comment on the proposed information collection.

The comment cited numerous problems that it stated were caused by the labeling requirement contained in § 610.40(h)(2)(vi), which requires each

donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results. For example, the comment stated that the labeling requirement ''causes unnecessary work and interrupts routine operations, thereby introducing risk of error, with no increase in safety.'' The comment also stated that the requirement ''generates inappropriate concerns on the part of healthcare personnel, transfusion recipients and their families.'' The comment asked that this requirement be deleted. These concerns pertain to matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

The comment also questioned FDA's estimate of 5 minutes in connection with § 610.40(h)(2)(vi). We had estimated that the time associated with the labeling requirement contained in this rule was 5 (4.8) minutes. The comment stated, ''Any non-routine activity that interrupts normal labeling operations, [sic] causes delays that take more than 4.8 minutes.'' The comment later went on to acknowledge that the application of a label to a unit, which is only one step in the labeling process, may take only five minutes. We wish to clarify that we only are referring to the application of a label to a unit in this proposed information collection. Therefore, consistent with the comment, our estimate remains the same.

Moreover, the comment referred to page 35697 and table 1 of the June 2008 document, and stated that ''FDA estimated that labeling directed and reactive or untested units for shipment would take five minutes. If labeling refers only to the application of the label to the unit, which is only one step in the labeling process, then 5 minutes may be adequate.'' We are unclear what the comment is referring to on page 35697 of the June 2008 document and note that table 1 refers to an estimate of 0.08 (4.8 minutes) with respect to §§ 610.40(c)(1)(ii), 610.40(h)(2)(vi), and 630.6(a). We are assuming that the comment is referring to the first two regulations, as the third goes to donor notification. We wish to clarify that in this information collection, we are only referring to the application of the label to the unit. Therefore, consistent with the comment, our estimate remains the same.

Finally, the comment pointed out an error in calculation of total hours associated with § 606.160(b)(1)(ix) in table 2 of the June 2008 document. The total hours calculated was listed as 875,000, instead of 87,500 (0.05 x 1,750,000). Therefore, the total estimated recordkeeping burden is 362,426. We have corrected this error accordingly.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(a)	353[5]	1.20	424	0.5	212
606.170(b)[2]	100	1	100	20	2,000
610.40(c)(1)(ii)	2,081	5.77	12,000	0.08	960
610.40(g)(2)	1	1	1	1	1
610.40(h)(2)(ii)(A)	1	1	1	1	1
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.2	96
610.40(h)(2)(vi)	2,081	8.65	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	2,000	5.25	10,500	0.17	1,785
610.46(a)(3)	2,000	5.25	10,500	0.17	1,785
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
610.47(a)(1)(ii)(B)	2,000	11.70	23,400	0.17	3,978
610.47(a)(3)	2,000	11.70	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
630.6(a)[3]	667	644.68	430,000	0.08	34,400
630.6(a)[4]	104	43.27	4,500	1.5	6,750
630.6(d)(1)	100	30	3,000	1	3,000
Total					64,487

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).
[3]Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4]Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.
[5]Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)[2]	353[5]	1	353	24	8,472
606.100(c)	353[5]	10	3,530	1	3,530
606.110(a)[3]	35[6]	1	35	0.5	18
606.151(e)	353[5]	12	4,236	0.083	352
606.160[4]	353[5]	793.20	280,000	0.75	210,000
606.160(b)(1)(viii)					
HIV consignee notification	2,000	10.50	21,000	.17	3,570
	4,980	4.21	21,000	.17	3,570
HCV consignee notification	2,000	23.40	46,800	.17	7,956
	4,980	9.4	46,800	.17	7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	349
606.160(b)(1)(ix)	2,081	840.94	1,750,000	0.05	87,500
606.160(b)(1)(xi)	2,000	3.375	6,750	0.05	338
606.165	353[5]	793.20	280,000	0.083	23,240
606.170(a)	353[5]	12	4,236	1.00	4,236
610.40(g)(1)	2,081	1	2,081	0.50	1,041
Total					362,426

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3]The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4]4 The recordkeeping requirements in §§ 640.3(a)(2) and (f); 640.4(a)(2); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.71(b)(1); 640.72; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5]Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).
[6]Five percent of plateletpheresis and leukopheresis establishments (0.05 x 696).

Dated: November 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26863 Filed 11–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0039]

Notice of Approval of Original Abbreviated New Animal Drug Application; Phenylbutazone Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for veterinary prescription use of phenylbutazone tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–433 providing for veterinary prescription use of Phenylbutazone Tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system. First Priority, Inc.'s, ANADA for Phenylbutazone Tablets is approved as a generic copy of First Priority, Inc.'s, PRIBUTAZONE Tablets, approved under NADA 48–647. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514), in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this ANADA is approved as of October 23, 2008.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 5, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–26793 Filed 11–10–08; 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 the Office of Management and Budget (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, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data Collection Worksheet Form (DCW): Reinstatement—(OMB No. 0915–0226)

The Data Collection Worksheet Form for the National Health Service Corps Scholarship Program enables the Division of Applications and Awards/Scholarship Branch (DAA/SB) within the Health Resources and Services Administration (HRSA) to obtain the costs charged by each health professions training program for tuition, fees, and other reasonable educational expenses, in order to determine the amount of each scholarship award. The DAA/SB enters this information into its computerized data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Worksheet	650	1	650	0.5	325
Total	650		650		325

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 4, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–26816 Filed 11–10–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

System for Correction of MRI Head Motion

Description of Technology: Motion artifacts continue to be a significant problem in MRI of human brain. Prospective motion correction based on external tracking systems has been proposed to ameliorate this issue. However, the calibration of these systems is very complicated and time consuming, as it requires a camera system calibration as well as a calibration between camera and MRI system using dedicated phantoms. An alternative motion correction method for MRI that does not require calibration and can work with just a single video camera has been developed and is available for licensing. This technology can be broadly applied in MRI to account for motion artifacts in order to improve acquisition time and provide enhanced resolution. This technique will provide a needed method to obtain reliable MRI scans for uncooperative patients (children, seizure patients, etc.)

without the need and expense of multiple scans.

Applications:

- Magnetic Resonance Imaging.
- Diagnostics.

Inventors: Jeff Duyn and Lei Qin (NINDS)

Publications:

1. JH Duyn, P van Gelderen, TQ Li, JA de Zwart, AP Koretsky, M Fukunaga. High-field MRI of brain cortical substructure based on signal phase. *Proc Natl Acad Sci USA*. 2007 Jul 10;104(28):11796–17801.
2. TQ Li, P van Gelderen, H Merkle, L Talagala, AP Koretsky, J Duyn. Extensive heterogeneity in white matter intensity in high-resolution T2*-weighted MRI of the human brain at 7.0 T. *Neuroimage*. 2006 Sep;32(3):1032–1040.

Patent Status: U.S. Provisional Application No. 61/045,782 filed 17 Apr 2008 (HHS Ref. No. E–144–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, PhD; 301–435–5236; *stansbej@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke—Advanced MRI Section—Laboratory of Functional and Molecular Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize MRI methods to improve data collection by improved homogeneity, resolution, etc. Please contact Dr. Melissa Maderia at 301–451–3943 or *maderiam@mail.nih.gov* for more information.

Methods for Using Interferon Gamma To Absorb Fluid From the Subretinal Space

Description of Technology: The accumulation of subretinal fluid is associated with certain adverse ocular conditions (including chronic macular edema, age related macular degeneration, and diabetic retinopathy), or retinal injury, or post-surgical complications. Often aberrant proliferation and migration of retinal pigment epithelial (RPE) cells is also associated with these ocular conditions. The RPE is a highly specialized derivative of the neuroectoderm with multiple roles in the maintenance of normal ocular function. Dysfunction of RPE cells has been implicated in inflammatory, degenerative, and dystrophic diseases of the retina and choroid. Interferon gamma (IFNγ) has been implicated in the pathogenesis of a number of intraocular inflammatory diseases of infectious or presumed autoimmune origin. IFNγ has been detected in vitreous aspirates of patients with uveitis, proliferative vitreoretinopathy, and idiophathic inflammatory eye diseases.

The technology provides for methods by which interferon-gamma (IFN-γ) can be used to remove subretinal fluid. The application of INF-γ may be by external application (e.g. eye drops or ointments) or by subretinal injection. The claims in the pending patent application are directed to methods for treating decreases in visual acuity that are associated with diseases that cause the accumulation of fluid in the subretinal space. Additional claims are directed at methods for treating age-related macular degeneration, chronic macular edema, diabetic retinopathy, retinal detachment, or glaucoma that comprise decreasing the amount of fluid present in the subretinal space of patients suffering from such disorders by administering an amount of interferon gamma to the eyes of the patients effective to decrease the amount of fluid present in the subretinal space of the patients.

Applications:

- Treatment and prevention of age-related macular degeneration (AMD), chronic macular edema, diabetic retinopathy, retinal detachment, or glaucoma.
- Treatment of decreases in visual acuity that are associated with diseases that cause the accumulation of fluid in the subretinal space.

Market: Diabetic retinopathy and age-related macular degeneration are the leading causes of blindness for those above age 45 and 60, respectively. These two diseases account for approximately 6–7 million cases of blindness each year in the U.S.

Development Status: Preclinical and animal model studies are in progress.

Inventors: Rong Li, Sheldon S. Miller, and Arvydas Maminishkis (NEI).

Patent Status: U.S. Provisional Application No. 61/089,157 filed 15 Aug 2008 (HHS Reference No. E–169–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, PhD, JD; 301–435–5020; vepas@mail.nih.gov.

Collaborative Research Opportunity: The National Eye Institute, Section on Epithelial and Retinal Physiology and Disease, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods that activate immune system mediated fluid removal from the distal retina. Please contact John D. Hewes, PhD at 301–435–3121, or *hewesj@mail.nih.gov* for more information.

Retinal Pigment Epithelia-Enriched MicroRNAs To Prevent Cell-Differentiation, Proliferation, and Migration

Description of Technology: The retinal pigment epithelium (RPE) plays a significant role in regulating the microenvironment around the photoreceptors in the distal retina, where the events of phototransduction take place.

Expression profiling of microRNA (miRNAs) in RPE and the adjacent retina and choroid was used to identify six miRNAs enriched in RPE. The potential use of anti-miRNAs specifically directed against miRNA 204 and miRNA 211 to prevent epithelial cell differentiation, proliferation and migration is disclosed. The miRNA 204 and miRNA 211 play a critical role in the control transepithelial electrical resistance. This technology further describes the significance of miRNAs in regulating junctional complexes in epithelial cells.

The claims in the pending patent application are directed towards methods and compositions containing anti-miRNAs or miRNA mimics for preventing or treating detrimental epithelial cell proliferation or loss of epithelial cell differentiation.

Applications:

- Treatment and prevention of age-related macular degeneration (AMD) and proliferative vitreal retinopathy.
- Treatment and prevention of neovascular diseases and carcinoma.

Market: AMD is the most common cause of adult blindness in Western, developed countries. A recent study has estimated that advanced AMD affects about 1.75 million Americans.

Development Status: Preclinical animal model studies and gene knockout studies are in progress.

Inventors: Fei Wang and Sheldon Miller (NEI).

Patent Status: U.S. Provisional Application No. 61/043,330 filed 08 Sep 2008 (HHS Reference No. E–056–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, PhD, JD; 301–435–5020; *vepas@mail.nih.gov.*

Collaborative Research Opportunity: The National Eye Institute, Section on Epithelial and Retinal Physiology and Disease, is seeking statements of capability or interest from parties interested in collaborative research to

further develop, evaluate, or commercialize the use of RPE-specific micro RNAs or anti-miRNAs or miRNA mimics for the treatment and prevention of age-related macular degeneration (AMD) and proliferative vitreal retinopathy and more generally for preventing or treating detrimental epithelial cell proliferation or loss of epithelial cell differentiation, e.g., in the treatment and prevention of neovascular diseases and carcinoma. Please contact John D. Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Human Monoclonal Antibodies Against *Yersinia pestis*

Description of Technology: The technology describes a group of three (3) human monoclonal antibodies directed against the *Yersinia pestis (Y. pestis)* bacterium, the etiologic pathogen of the fatal disease Plague. These antibodies are specifically directed against two of the bacterium's virulent factors, the F1 capsid protein (one antibody) and the low-calcium response antigen V (LcrV) (two antibodies). The antibodies have been shown to provide protection against *Y. pestis* challenge in a mouse model, with the highest protection attained with a combination of all three. The NIH offers the subject antibodies for licensing primarily for the development of therapeutic and/or prophylactic treatment against *Y. pestis* infections. Additionally, the antibodies may find use in research related to the pathogenicity of *Y. pestis* as well as for the development of new treatment against this pathogen.

Although human plague in the United States has occurred as mostly scattered cases in rural areas (an average of 10 to 15 persons each year), and globally, according to the World Health Organization, there are only 1,000 to 3,000 cases of plague every year, it is however of significant importance to develop effective treatment against the plague disease, because of its biodefense significance. *Y. pestis* is included in the CDC and NIH's category A agents that can be readily used as a biological weapon in the hands of bioterrorists.

Applications:

• The antibodies offered for licensing can be used to develop therapeutic and/or prophylactic treatment against *Y. pestis,* the causative pathogen of Plague, which can be readily used as a biological weapon and thus has been considered a category A biodefense agent by the CDC and NIH.

• The antibodies offered for licensing may find use in research related to *Y. pestis* and for development of new treatment against Plague.

Advantages: Currently there is no effective therapeutic or prophylactic treatment available against plague. Antibiotics are primarily used to treat persons infected with *Y. pestis.*

Market:

• Plague, the disease caused by *Y. pestis,* is characterized by symptoms such as fever, chills, cough and difficulty in breathing. If not treated early, the disease can lead to death.

• Although the market size for treating plague is small (1,000 to 3,000 worldwide cases every year and 10 to 15 cases in the United States), a development of effective treatment is of utmost importance as the bacterium can be used as a biological weapon. It is therefore included in the list of category A biodefense agents as defined by the CDC and NIH, and received a significant attention with respect to preparedness against bioterrorism.

Development Status:

• The inventors have demonstrated the protective effectiveness of the antibodies using model mice challenged with the bacterium.

• Further development including clinical trials will be needed to develop the technology to the point of practical application.

Inventors: Dimiter S. Dimitrov (NCI), Xiaodong Xiao (NCI), *et al.*

Relevant Publications:

1. RD Perry and JD Fatherston. Yersinia pestis—etiologic agent of plague. *Clin Microbiol Rev.* 1997 Jan;10(1):35–66.

2. J Hill, SE Leary, KF Griffin, ED Williamson, RW Titball. Regions of Yersinia pestis V antigen that contribute to protection against plague by passive and active immunization. *Infect Immun.* 1997 Nov;65(11):4476–4482.

3. GW Anderson Jr, PL Worsham, CR Bolt, GP Andrews, SL Welkos, AM Friedlander, JP Burans. Protection of mice from fatal bubonic and pneumonic plague by passive immunization with monoclonal antibodies against F1 protein of Yersinia pestis. *Am J Trop Med Hyg.* 1997 Apr;56(4):471–473.

Patent Status: HHS Reference No. E–013–2008—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: The technology is available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Uri Reichman, PhD; 301–435–4616; *reichmau@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute CCRNP, Protein Interactions Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize human monoclonal antibodies against Yersinia Pestis. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Related Technology: U.S. Patent Application No. 11/944,230 filed 21 Nov 2007 (HHS Reference No. E–189–2007/0), entitled ''Manufacturing Process Improvements for Purification of F1–V as a Vaccine Potentially Protective Against Bubonic and Pneumonic Plague,'' by Steven L. Giardina and David F. Nellis (NIAID)

Viral Inactivation Using Crosslinkers and Detergents

Description of Technology: The subject technology is a method of inactivating enveloped viruses by hydrophobic photoactivatable chemical crossing-linking compounds and detergent treatment. The inactivated viruses may be used as vaccines against the diseases caused by those viruses or as reagents in experimental procedures that require inactivated viral particles. The compounds diffuse into the lipid bilayer of biological membranes and upon UV irradiation will bind to proteins and lipids in this domain, thereby inactivating fusion of enveloped viruses with their corresponding target cells. Furthermore, the selective binding of these chemical crosslinking agents to protein domains in the lipid bilayer may preserve the structural integrity and therefore immunogenicity of proteins on the exterior of the inactivated virus. The additional detergent step effectively eliminates the infectivity of any residual viral particles that are not adequately crosslinked.

Applications:

• Vaccines for enveloped viruses

• Vaccine for Human Immunodeficiency Virus

Advantages:

• Novel method of inactivating enveloped viruses

• May maintain native conformational structures and viral epitopes for generating an effective immune response

Development Status: In vitro data can be provided upon request

Market: Vaccines

Inventors: Julie M. Belanger *et al.* (NCI)

Patent Status:

• U.S. Provisional Application No. 61/025,424 filed 01 Feb 2008 (HHS Reference No. E–331–2007/0–US–01)

• U.S. Provisional Application No. 61/088,294 filed 12 Aug 2008 (HHS Ref. No. E–331–2007/1–US–01)

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of hydrophobic crosslinkers for their use in vaccine development. Interested collaborators are also invited to provide statements for proposed *in vitro* or *in vivo* studies using various enveloped viruses. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Indoline Compounds for the Treatment of Spinal Muscular Atrophy (SMA) and Other Diseases

Description of Technology: With the goal to treat SMA in patients, several indoline compounds were made and tested for activity. Tests in cells demonstrate that these drugs increased the levels of active SMN protein. This is encouraging since low levels of this protein appears to be the cause of neuronal death that leads to SMA. This class of compounds appears to operate via read-through of a non-sense stop-codon to produce full length, functional protein in SMA models. This mechanism may have utility in several other neurological disorders, including cystic fibroses and Duchene's Muscular Dystrophy.

In addition, these compounds have also been shown to increase the concentration of a glutamate transporter protein in cells, which acts to recover glutamate back into neurons after release. Since the toxic effect of unrecovered excess glutamate is observed in many notorious neurological conditions, these compounds have potential for prevention or treatment.

Applications:

- Treatment of SMA in infants and children.
- Treat genetic-based diseases that result from a premature stop of protein synthesis such as muscular dystrophy and cystic fibrosis.
- Treating or preventing neurological diseases presenting glutamate toxicity like multiple sclerosis, Parkinson's, Alzheimer's, amyotrophic lateral sclerosis (ALS), or others.

Market:

- SMA is a rare genetic disease estimated to affect 1 in 6,000 births and leading genetic cause of death in infants and toddlers.
- Over 25,000 Americans are believed to suffer from SMA and the market size has been estimated between $250 million and $750 million.

Development Status: Pre-clinical, Toxicology and Safety Studies, Animal Models (Dogs and Primates).

Inventors: Jill E. Heemskerk (NINDS) *et al.*

Related Publication: MR Lunn, DE Root, AM Martino, SP Flaherty, BP Kelley, DD Coovert, AH Burghes, NT Man, GE Morris, J Zhou, EJ Androphy, CJ Sumner, BR Stockwell. Indoprofen upregulates the survival motor neuron protein through a cyclooxygenase-independent mechanism. *Chem Biol.* 2004 Nov;11(11):1489–1493.

Patent Status:

- U.S. Provisional Application No. 60/975,675 filed 27 Sept 2007 (HHS Reference No. E–187–2007/0–US–01);
- PCT Application No. PCT/US2008/077936 filed 26 Sep 2008 (HHS Reference No. E–187–2007/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Norbert Pontzer, PhD, JD; 301–435–5502; *pontzern@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize drugs for the treatment of SMA, as well as investigation into novel uses for these indoline compounds. Please contact Dr. Melissa Maderia at *maderiam@mail.nih.gov* or 301–451–3943 for more information.

Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy

Description of Technology: This invention describes small cDNA fragments of the coding region for wild type filamin A interacting protein 1-like (FILIP1L), previously known as *down-regulated in ovarian cancer 1-like* (DOC1) and variant 2 of FILIP1L genes that encode proteins that result in the inhibition of cell migration and motility, induce cell apoptosis and inhibit cell proliferation. These effects can be seen on endothelial cells and on tumor cells. These coding sequences have successfully been delivered to endothelial cells and tumor cells both in vitro and in vivo, and have demonstrated significant anti-tumor activity. In addition, the inventors have for the first time expressed the recombinant protein and developed antibodies to detect the protein fragments by Western, ELISA and immunohistochemistry. The significance of this invention is that it could provide for a series of new anti-cancer therapeutics and for the diagnostic means to follow their expression levels.

Applications: This invention could provide new anti-cancer therapeutics and diagnostics.

Market:

- An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.
- 600,000 deaths caused by cancer in the U.S. in 2006.
- Cancer is the second leading cause of death in the U.S.
- Cancer drug market will likely double to $50 billion in 2010 from $25 billion in 2006.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Steven K. Libutti et al. (NCI).

Relevant Publication: Mijung Kwon et al. Functional characterization of filamin A interacting protein 1-like, a novel candidate for antivascular cancer therapy. *Cancer Res.* 2008 Sep 15;68(18):7332–7341.

Patent Status: U.S. Provisional Application No. 61/005,363 filed 03 Dec 2007 (HHS Reference No. E–166–2007/0-US–01).

Licensing Status: Available for exclusive and non-exclusive license.

Licensing Contact: Adaku Nwachukwu, JD; 301–435–5560; *madua@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Hatfield Clinical Research Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–26786 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Therapeutic Targeting of CSN5, a Negative Regulator of p53 and p27, in Human Hepatocellular Carcinoma

Description of Technology: Hepatocellular carcinoma (HCC) represents an extremely poor prognostic cancer that remains one of the most common and aggressive malignancies worldwide. Elevated expression of COP9 complex homolog subunit 5 (CSN5) in early HCC indicates that CSN5 is one of the early markers of malignant conversion. COP9 complex homolog subunit 5 (CSN5) is a multifunctional protein that interacts with a variety of proteins and targets p53 for cell degradation.

Available for licensing are CSN5 siRNAs and nucleic acid-lipid siRNA particles as cancer therapies. HCC cells treated with CSN5 siRNAs inhibited HCC progression and increased apoptosis *in vitro* and *in vivo* suggesting that CSN5 is an effective target for the development of cancer treatments.

Applications:

- siRNA cancer therapeutics.
- Nucleic acid-lipid siRNA particles for targeted drug delivery.
- Method to treat cancer.

Development Status: Early stage of development.

Market:

- HCC is the most frequent primary malignant tumor of the liver with a world incidence of 1 million new cases per year.
- The global cancer therapeutic market is expected to grow from $23.1 billion in 2004 to $60.6 billion in 2011. The targeted therapy segment is providing the growth of the entire market with an expected compound annual growth rate of 24.1 percent for 2004–2011.

Inventors: Snorri Thorgeirsson (NCI), Yun-Han Lee (NCI), *et al.*

Patent Status: U.S. Provisional Application No. 61/045,251 filed 15 Apr 2008 (HHS Reference No. E–174–2008/0–US–01).

Publication: JS Lee *et al.* Classification and prediction of survival in hepatocellular carcinoma by gene expression profiling. *Hepatology* 2004 Sept;40(3):667–676.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Computer Aided Scoring and Analysis (CASA) for Rapid and Robust Detection of Biological Molecules in Tissue Microarrays

Description of Technology: Tissue Microarray (TMA) technology is a technique that allows tissue samples to be miniaturized and biologically characterized. The results can be stored digitally and analyzed manually for the expression of biological molecules which can permit the diagnosis or prognosis of disease. Despite its practical use, the current method of manually analyzing TMA samples is subjective and lacks the standardization and concordance needed to support consistent interpretation of the results. This leads to a low correlation in the results obtained amongst different laboratories and detection agents.

The current invention, Computer Aided Scoring and Analysis (CASA), provides a means of rapidly and consistently analyzing the expression patterns of biological molecules in large quantities of tissue samples. This software uses novel algorithms which normalize the pixel data obtained from digital images of the samples, statistically determines which biological molecules are diagnostic markers for the disease, and compares these data to normal, as well as diseased or abnormal tissue samples, to diagnose or predict susceptibility to the disease. In some applications, two or more biological molecules can be simultaneously screened or identified using two or more detection agents making the CASA system amenable to methods such as cluster analysis. This type of analysis can not only identify groups of antigens that are associated with a disease, but can also combine this information with characteristics of the patient population, such as age, gender or ethnicity to achieve a predictive output. The CASA system can analyze data from a broad range of detection agents such as antibodies, radionuclides, dyes and quantum dots making it a very attractive tool for high throughput TMA analysis.

The system has already been used successfully for the diagnosis and prognosis of non-small cell lung cancer in tissue samples and can be adapted for use in many diseases where changes in the expression of one or more biological molecules will to be detected.

Applications:

- Large scale diagnosis of tissue expression patterns of biological molecules.
- Rapid, robust tissue diagnosis or prognosis of disease.
- Compatible with wide range of detection agents.

Development Status: Early Stage.

Inventors: Abbas Shakoori and Jin Jen (NCI).

Patent Status: U.S. Provisional Application No. 61/034,868 filed 07 Mar 2008 (HHS Reference No. E–126–2008/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Predictive Test for Age-Related Macular Degeneration in Asymptomatic Individuals

Description of Technology: Age-related macular degeneration (ARMD) is the leading cause of severe, irreversible vision loss for those over the age of fifty in the United States and in other developed countries. Thirteen million Americans over the age of forty have ARMD. ARMD is caused by the deterioration of the central area of the retina, or macula, resulting in a loss of central vision. This disease is believed to be a multigenic disorder, and is triggered by environmental factors such as smoking, age or diet in genetically susceptible individuals.

The present invention describes a highly predictive genetic test for universal practical clinical use to identify individuals at increased risk for ARMD. It comprises a rapid, accurate and affordable genetic screen, utilizing DNA microarray technology on a single chip. Sixteen genes are screened for 90 mutations/polymorphisms associated with ARMD, with a high predictive power (up to 92.7%) to identify asymptomatic carriers at risk. Accurate prediction of genetic susceptibility to this disorder will allow interventions to protect at-risk individuals.

Applications:

- Method to diagnose ARMD.
- Diagnostic kit to identify asymptomatic individuals at risk for ARMD.
- Method to identify genetic factors in an affected individual, aiding in the

development of a tailored therapeutic plan.

• Provide genetic epidemiologic data to elucidate the role of genetic factors in the progression of the disease.

Advantage: Easy, rapid high-throughput method to diagnose ARMD.

Development Status: This technology requires analytic validation before commercialization.

Market: There are an estimated 15 million cases of age-related macular degeneration in the United States, and 50 million cases worldwide.

Inventors: Cigdem F. Dogulu, Owen M. Rennert, Wai-Yee Chan (NICHD)

Patent Status:

• U.S. Patent Application No. 12/089,694 filed 09 Apr 2008 (HHS Reference No. E–023–2006/0–US–07).

• Australian Patent Application No. 2006311966 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–AU–03).

• Canadian Patent Application No. 2,627,686 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–CA–04).

• European Patent Application No. 06836855.4 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–CA–04).

• Japanese Patent Application No. 2008–539046 filed 01 May 2008 (HHS Reference No. E–023–2006/0–JP–06).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The NICHD Section on Clinical Genomics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Method Evolved for Recognition and Testing of Age-Related Macular Degeneration (MERT–ARMD). Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–26787 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Radiation Induced and Targeted Chemotherapy

Description of Technology: The invention relates to a novel method of targeted chemotherapy for the treatment of cancer using hydrophobic photoactivatable compounds like 1,5-iodoanpthylazide (INA) and its analogues. The invention evolved from the discovery that electron dense atom-containing photoactivatable compounds can be activated by radiation (i.e., by x-rays and/or ultrasound) to form reactive intermediates that are highly toxic to living cells. Such compounds are termed ''radiation-activatable'' compounds. These radiation-activatable compounds do not become toxic until activated by radiation which allows for the targeting of the toxic compound by irradiation. Preliminary in vitro data show that INA and its derivatives can quickly and efficiently kill tumor cell lines upon irradiation.

Applications: Cancer Treatment.

Advantages: Novel method of cancer treatment.

Development Status: In vitro data can be provided upon request.

Market: Cancer Therapy.

Inventors: Yossef Raviv *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/026,654 filed 06 Feb 2008 (HHS Ref. No. E–256–2007/0-US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Kevin W. Chang, PhD, 301–435–5018, *changke@mail.nih.gov.*

Small-Molecule Modulators of the Thyroid-Stimulating Hormone (TSH) Receptor

Description of Technology: The thyroid gland plays a major role in the body, secreting hormones that regulate the metabolic rate, production of other hormones, and the growth and maturation of body tissues. Thyroid disorders affect energy metabolism, neurological state, fertility, cardiovascular condition, and other body functions. In patients with hyperthyroidism, or an overactive thyroid gland, the disease is often caused by autoimmune over-stimulation of the thyroid gland (Graves' disease), or by thyroid tumors. Drugs currently used for short-term treatment of hyperthyroidism inhibit synthesis of thyroid hormones, although long-term treatment usually requires removal of the thyroid gland by surgery or administration of radioiodine. Hypothyroidism, or an underactive thyroid gland, can be caused by autoimmune disease, atrophy of the thyroid gland, or through a deficiency of thyroid-stimulating hormone (TSH). TSH, produced by the pituitary gland, binds to the TSH receptor in the thyroid to stimulate thyroid hormone production. Hypothyroidism is typically treated by direct replacement of the thyroid hormones.

The inventors have discovered a series of low-molecular weight compounds that act as TSH receptor antagonists (inhibitors) or agonists (activators). Antagonists of the TSH receptor could be used to treat hyperthyroidism, with the advantage of directly downregulating the TSH receptor, rather than inhibiting thyroid hormone synthesis. Agonists of the TSH receptor could be used to monitor thyroid activity and potential cancer recurrence in patients who have been treated for thyroid cancer, and may also be useful for treatment of certain forms of hypothyroidism. Additionally, some compounds in this family may be useful for treatment of fertility and reproductive disorders involving the luteinizing hormone/choriogonadotropin (LH/CG) receptor and the follicle-stimulating hormone (FSH) receptor, which are structurally related to the TSH receptor.

Applications:

• Development of therapeutics for hyperthyroidism or hypothyroidism.

• Development of diagnostic tools for evaluation of thyroid cancer patients.

• Development of therapeutics for infertility.

Market: Approximately 1 in 13 Americans suffers from a thyroid

disorder, and 10 million have a thyroid-related condition that requires ongoing immunodiagnostic monitoring.

Development Status: Early stage.

Inventors: Marvin C. Gershengorn *et al.* (NIDDK).

Publications:

1. S Moore, H Jaeschke, G Kleinau, S Neumann, S Costanzi, JK Jiang, J Childress, BM Raaka, A Colson, R Paschke, G Krause, CJ Thomas, MC Gershengorn. Evaluation of small-molecule modulators of the luteinizing hormone/choriogonadotropin and thyroid stimulating hormone receptors: structure-activity relationships and selective binding patterns. *J Med Chem.* 2006 Jun 29;49(13):3888–3896.

2. S Titus, S Neumann,W Zheng, N Southall, S Michael, C Klumpp, A Yasgar, P Shinn, CJ Thomas, J Inglese, MC Gershengorn, CP Austin. Quantitative high throughput screening using a live cell cAMP assay identifies small molecule agonists of the TSH receptor. *J Biomol Screen.* 2008 Feb;13(2):120–127.

3. S Neumann, G Kleinau, S Costanzi, S Moore, BM Raaka, CJ Thomas, G Krause, MC Gershengorn: A low molecular weight antagonist for the human thyrotropin receptor with therapeutic potential for hyperthyroidism. *Endocrinology.* 2008 31 Jul; published online ahead of print, doi:10.1210/en.2008–0836.

Patent Status: International Patent Application No. PCT/US2007/011951 filed 17 May 2007 (HHS Reference No. E–223–2006/0-PCT–02).

Licensing Status: This technology is available for exclusive, co-exclusive, or nonexclusive licensing.

Licensing Contact: Tara L. Kirby, PhD; 301–435–4426; *tarak@mail.nih.gov.*

Methods for Accurately Measuring and Regulating Bound Adrenomedullin

Description of Technology: This technology involves an array of applications relating to a key discovery regarding adrenomedullin-binding proteins.

Adrenomedullin (AM) is a ubiquitously expressed peptide first found in human pheochromocytoma, a cancer of the adrenal medulla. AM appears to function as a universal autocrine growth factor, driving cell proliferation, as a vasodilator, as a mechanism for protecting cells against oxidative stress in hypoxic injury, and as a dose-dependent inhibitor of insulin secretion. Accordingly, methods for measuring in vivo levels of AM accurately, and methods for regulating the activity of available AM, may be critically important in diagnosis and treatment of many conditions, such as heart disease, pulmonary disease, liver cirrhosis, cancer, diabetes, sepsis, and inflammation.

The present technology centers on the observation that AM binds to Complement Factor H (CFH) in vivo. Without a means to determine the amount of AM that is bound to CFH, measurements of AM are inaccurate, and therapies focused on the AM-CFH complex may have advantages compared to therapies focused on AM alone.

The technology includes methods for measuring and utilizing purified AM-binding proteins, or functional portions thereof, to diagnose, treat, and monitor AM-related diseases. A second aspect includes the identification and isolation of the AM-CFH complex. Antibodies and small-molecule antagonists (which can down-regulate the function of AM, CFH, and the AM-CFH complex) have also been isolated. Collectively, the technology provides methods for diagnosis and treatment of conditions such as cancer, diabetes, or other conditions that are influenced by AM levels.

Applications and Advantages:

- More accurate measurements of serum adrenomedullin than current tests
- Antibodies targeting AM-CFH decrease bioavailable AM, which may be useful in suppressing angiogenesis in cancers
- Antibodies targeting the CFH binding site increase bioavailable AM, which may be useful in therapies involving vasodilation, angiogenesis, and tolerance for hypoxic or ischemic injury during stroke or myocardial infarction

Development Status: In vivo and *in vitro* proof of concept data are available.

Inventors: Frank Cuttitta *et al.* (NCI).

Related Publications:

1. AJ Dwivedi *et al.* Adrenomedullin and adrenomedullin binding protein-1 prevent acute lung injury after gut ischemia-reperfusion. *J Am Coll Surg.* 2007 Aug;205(2):284–293.

2. D Ajona *et al.* Down-regulation of human complement factor H sensitizes non-small cell lung cancer cells to complement attack and reduces in vivo tumor growth. *J Immunol.* 2007 May 1;178(9):5991–5998.

3. A Martínez *et al.* Mapping of the adrenomedullin-binding domains in human complement factor H. *Hypertens Res.* 2003 Feb;26 Suppl:S55–59.

4. R Pio *et al.* Complement factor H is a serum-binding protein for adrenomedullin, and the resulting complex modulates the bioactivities of both partners. *J Biol Chem.* 2001 Apr 13;276(15):12292–12300.

Patent Status: HHS Reference No. E–256–1999/0–

- U.S. Patent Application No. 11/530,441 filed 08 Sept 2006, claiming priority to 10 Sept 1999
- Foreign counterparts in Australia, Canada, France, Germany, Great Britain, Italy, Spain, and Portugal

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Tara L. Kirby, PhD; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute (NCI)/Angiogenesis Core Facility is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize AM-CFH complex involvement with tumor angiogenesis and identifying potential Rxs to disrupt this effect. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–26790 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Microarray for Detection and Subtyping of Human Influenza Viruses

Description of Technology: Available for licensing and commercial development are a novel influenza virus microarray and methods for using the microarray for the identification of existing and new types and subtypes of human influenza viruses. There are three types of influenza viruses, type A, B and C. Influenza types A or B viruses cause epidemics of disease almost every winter, with type A causing a major pandemic periodically. Influenza type A viruses are further divided into subtypes based on two proteins on the surface of the virus. These proteins are called hemagglutinin (H) and neuraminidase (N). There are 16 known HA subtypes and 9 known NA subtypes of influenza A viruses. Each subtype may have different combinations of H and N proteins. Although there are only three known A subtypes of influenza viruses (H1N1, H1N2, and H3N2) currently circulating among humans, many other different strains are circulating among birds and other animals and these viruses do spread to humans occasionally. There is a requirement for sensitive and rapid diagnostic techniques in order to improve both the diagnosis of infections and the quality of surveillance systems. This microarray platform tiles the genomes of all types/subtypes of influenza viruses, and is capable of correctly identifying all 3 types/subtypes of influenza viruses from an influenza vaccine sample.

More specifically, the invention consists of: (1) Microarrays comprising a solid support with a plurality of n-mer influenza viral nucleotide segments of influenza Types A, B and C, including each respective subtype, and (2) methods of detecting and identifying known and unknown influenza viral types and subtypes by: (a) Using hybridization microarrays to known influenza viral nucleotide sequences, (b) sequencing the nucleotides which hybridize to the microarrays and (c) analyzing the hybridized sequences using existing databases, thus identifying existing or new subtypes of influenza viruses.

Applications: Detection and identification of human influenza viruses; Efficient discovery of new subtypes of influenza viruses; Diagnosis of influenza outbreaks.

Development Status: This microarray platform was capable of correctly identifying all 3 types/subtypes of influenza viruses from an influenza vaccine sample.

Inventors: Xiaolin Wu, Cassio S. Baptista, Elizabeth Shannon, and David J. Munroe (NCI).

Patent Status:

- U.S. Provisional Application No. 60/857,695 filed 07 Nov 2006 (HHS Reference No. E–208–2006/0–US–01);
- U.S. Patent Application No. 11/936,530 filed 07 Nov 2007 (HHS Reference No. E–208–2006/0–US–02);
- PCT Application No. PCT/US2007/023448 filed 07 Nov 2007 (HHS Reference No. E–208–2006/0–PCT–03).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov.*

Novel Infrared (IR)-Transparent Hydrophilic Membrane That Can be Used for Filtration, Printing or Microarrays, and Cultivation of Bacteria and Other Microorganisms for Reagent-Free IR Spectroscopic Identification

Description of Technology: Available for licensing and commercial development is a novel, disposable infrared (IR)-transparent, microporous, plasma treated polyethylene hydrophilic membrane, as well as methods for making and using this membrane to identify bacterial and other micoorganism impurities in food using IR spectroscopy. Further applications include: Filtering dilute aqueous bacterial suspensions, and growing bacterial colonies when the PE membrane is placed over an agar medium and incubated. The patent also describes a novel high-throughout technique, as an alternative to manual filtration, where the PE membrane is used for microarray printing of intact microorganisms in pre-enriched medium on the treated PE substrate. Furthermore, the invention relates to a method of detecting mixtures of food-borne pathogens *E. sakazakii* and *K. pneumonia*, by using the treated PE membranes. Because this unique membrane is transparent to infrared light, isolated microcolonies of bacterial cells grown on this PE substrate can be fingerprinted directly by IR microspectroscopy, followed by multivariate analysis for the identification of the pathogens. The method can be applied to other cell types as well.

This novel membrane and its applications offer an advantage over existing tests in that it can be used to rapidly identify presumptive pathogen colonies, and can be used in screening tests for a large number of pathogens, as well as various microorganisms and cell types. It can also be used to isolate microorganisms from aqueous suspensions as well as spores, including airborne ones.

Inventors: Magdi M. Mossoba and Sufian Al-Khaldi (FDA).

Patent Status:

- U.S. Patent Application No. 11/343,561 filed 30 Jan 2006 (HHS Reference No. E–174–2005/0–US–01);
- U.S. Patent Application No. 12/150,048 filed 23 Apr 2008 (HHS Reference No. E–174–2005/0–US–02).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov.*

Molecular Motors Powered by Proteins

Description of Technology: The technology available for licensing and commercial development relates to molecular motors powered by proteins. Some implementations describe a molecular motor in which multiple concentric cylinders or nested cones rotate around a common longitudinal axis. Opposing complementary surfaces of the cylinders or cones are coated with complementary motor protein pairs, such as actin and myosin. The actin and myosin interact with one another in the presence of ATP to rotate the cylinders or cones relative to one another, and this rotational energy is harnessed to produce work. Speed of movement is controlled by the concentration of ATP and the number of nested cylinders or cones. The length of the cylinders or cones can also be used to control the power generated by the motor.

Another configuration forms the motor out of a set of stacked disks, much like CDs on a spindle. The advantage of this form is extreme simplicity of construction compared to the nested cylinders or cones. In yet another configuration, which has aspects of both of the previous forms, the surfaces are broken into annular rings in order to overcome that the inner surfaces rotate at a different rate than the outer surfaces. This belt form may ultimately be used in molecular manufacturing.

Applications:

- Supplying power to prosthetic implants and other medical devices without external power sources.
- Many other applications that could use a motor in other biotechnological areas, in addition to the medical applications.
- The inventions can be implemented on either a microscopic or macroscopic scale.

Development Status: Very early stage of development.

Inventors: Thomas D. Schneider and Ilya G. Lyakhov (NCI).

Relevant Publications: ''Molecular motor'', Patent Publication Nos. WO 2001/009181 A1, published 02/08/2001; CA 2380611A1, published 02/08/2001; AU 6616600A, published 02/19/2001; EP 1204680A1, published 05/15/2002; and U.S. 20020083710, published 07/04/2002.

Patent Status:

• HHS Reference No. E–018–1999/0—International Application Number PCT/US 2000/20925 filed 31 Jul 2000; granted Application AU 2002/18688 B2, and the corresponding European and Canadian applications being prosecuted, all entitled ''Molecular Motor''

• HHS Reference No. E–018–1999/1—U.S. Patent No. 7,349,834 issued 25 Mar 2008, and U.S. Patent Application No. 12/011,239 filed 24 Jan 2008, both entitled ''Molecular Motor''

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the Molecular Rotation Engine. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–26794 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel Small Business: Orthopaedics and Skeletal Biology.

Date: November 18, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree Hotel, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

Contact Person: John P. Holden, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, *holdenjocsr.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: Center for Scientific Review Special Emphasis Panel Behavioral and Social HIV/AIDS Review of SBIR Applications.

Date: November 24, 2008.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertmcsr.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: Center for Scientific Review Special Emphasis Panel SBIR Environmental Monitoring and Remediation.

Date: December 2–3, 2008.

Time: 8 a.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 5144, MSC 7812, Bethesda, MD 20892, 301–435–2902, *gubina@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel AIDS Fellowship Application Review.

Date: December 2–3, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Brain Disorders and Clinical Neuroscience Member Conflict.

Date: December 2, 2008.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jay Joshi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 435–1184, *joshij@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Kidney Dialysis, Monitoring and Therapeutics Small Business Applications Review.

Date: December 10–11, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Krystyna E. Rys-Sikora, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016J, MSC 7814, Bethesda, MD 20892, 301–451–1325, *ryssokok@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflicts: Neurobiology.

Date: December 10–11, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Christine L. Melchior, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1713, *melchioccsr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Heart Metabolism and Physiology.

Date: December 11–12, 2008.

Time: 1 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Larry Pinkus, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkuslcsr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 3, 2008.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26684 Filed 11–10–08; 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; Career Enhancement Award (K18).

Date: December 3, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Yingying Li-Smerin, MD, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924, 301–435–0277, *lismerin@nhlbi.nih.gov.*

(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: November 4, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26789 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

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 of Dental & Craniofacial Research, 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, National Institute of Dental and Craniofacial Research.

Date: December 7–9, 2008.

Time: December 7, 2008, 7 p.m. to 9:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, 30 Convent Drive, 117, Bethesda, MD 20892.

Time: December 8, 2008, 8 a.m. to 8 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, 30 Convent Drive, 117, Bethesda, MD 20892.

Time: December 9, 2008, 8 a.m. to 2:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, 30 Convent Drive, 117, Bethesda, MD 20892.

Contact Person: Norman S. Braveman, Assistant to the Director, NIH—NIDCR, 31 Center Drive, Bldg. 31, Room 5b55, Bethesda, MD 20892, (301) 594–2089, *norman.braveman@nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about/CouncilCommittees.asp*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: November 4, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26779 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Non-Invasive Diabetes Diagnostics

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), a federal agency under the Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the invention embodied in HHS Ref. Nos. E–091–1998 ''Method For Non-Invasive Identification Of Individuals At Risk For Diabetes;'' U.S. Patent No. 6,721,583; and HHS Ref. No. E–079–1998 ''Optical Fiber Probe and Methods for Measuring Optical Properties;'' U.S. Patent No. 6,678,541; to Eyelight Diagnostics, Inc., a corporation formed under the laws of the state of Connecticut and having a principle place of business therein. The United States of America is the assignee of the patent rights in the above inventions.

The contemplated exclusive license may be granted in a field of use limited to devices and integrated systems for non-invasive ocular clinical diagnostics for diabetes.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before January 12, 2009 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; *Facsimile:* (301) 402–0220; *E-mail: shmilovm@mail.nih.gov.* A signed confidentiality nondisclosure agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patent applications intended for licensure disclose and/or cover the following:

E–079–1998 ''Method For Non-Invasive Identification of Individuals at Risk for Diabetes''

The invention describes a fiber optic probe assembly and methods of using the probe for both medical diagnostic and industrial applications. This device consists of a single light delivery source in combination with an array of light detector fibers. In use, the assembly has the ability to simultaneously acquire data from a variety of source/detector separations. The entire data set is saved in a format, for use with an appropriate mathematical model of light transport, to deduce optical properties of the test sample. The properties may be associated with the technique known as ''optical biopsy'' for diagnostic purposes. Industrial applications where a turbid mixture requires analysis can also employ the disclosed device and methods. Examples of some industrial uses would be manufacturing processes associated with pharmacology, food processing, and emulsion technology.

E–091–1998 ''Optical Fiber Probe and Methods for Measuring Optical Properties''

The invention pertains to a non-invasive technique for the detection of ocular pathologies, including molecular changes associated with diabetes. Raman spectra emitted from the eye that is subject to a laser probe provides information regarding early markers of diabetes or diabetes-induced ocular pathologies. The invention compares spectra taken from the subject under study to spectra from a normal subject. Multivariate statistical methods are used to obtain predictive information based on the detected spectra, and to diagnose or predict the onset or stage of progression of diabetes-induced ocular pathology.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 3, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–26788 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Access to Recovery (ATR) Program Cross-Site Evaluation—New

SAMHSA's Center for Substance Abuse Treatment (CSAT) is conducting a cross-site evaluation of the Access to Recovery (ATR) program. CSAT's ATR program is a competitive, discretionary grant awarded to 18 States, the District of Columbia, and five Tribal Organizations to develop and operate a voucher-based substance abuse treatment financing system. The primary focus of the ATR program is to improve access by utilizing treatment payment vouchers, to expand independent client choice of treatment providers, to expand access to both clinical treatment and recovery support services (RSS), and to increase substance abuse treatment capacity by increasing the array of faith-based and community organizations through which clinical treatment and RSS can be offered. The purpose of the cross-site evaluation is to examine how grantees implement the ATR program and the program's impact on existing treatment systems and client outcomes and to inform future policy on the development and implementation of substance abuse treatment voucher systems.

Two surveys will be administered as part of this evaluation. One survey will be administered to a sample of clients participating in the ATR program and a second survey will be administered to service organizations participating in a grantee's ATR program. The client survey will be administered following the 6-month post-intake Government Performance and Results Act (GPRA) follow-up (OMB No. 0930–0208), using the same data collection methods as the GPRA data collection to reduce client burden. GPRA data collection methods vary by ATR grantee; typically, grantees collect GPRA data in-person, but in special cases they may use a telephone interview. The ATR client survey includes questions on client choice, ease of obtaining services through an ATR program, and client satisfaction. The provider survey will be administered through a Web survey instrument and will target a key informant in the organization to complete the survey. Providers unable to access or complete the Web survey will be provided with a paper version of the survey. The provider survey includes questions on organizational characteristics, satisfaction with the ATR program, and experience participating in the ATR program.

TOTAL BURDEN HOURS FOR THE CROSS-SITE CLIENT AND PROVIDER SURVEY

Instrument/activity	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours per collection
Client Survey	7,329	1	0.15	1,099
Provider Survey (80% response rate)	4,083	1	0.50	2,042
Total	11,412			3,141

Written comments and recommendations concerning the proposed information collection should be sent by December 12, 2008 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: November 4, 2008.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E8–26796 Filed 11–10–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Trustee Council; Renewal of the Public Advisory Committee

AGENCY: Office of the Secretary, Department of the Interior.

ACTION: Notice of Reestablishment.

In accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C., App. 2), following the recommendation and approval of the *Exxon Valdez* Oil Spill Trustee Council, and in consultation with the General Services Administration the Secretary of the Interior hereby renews the charter for the *Exxon Valdez* Oil Spill Public Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Room 119, Anchorage, Alaska, (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Court Order establishing the *Exxon Valdez* Oil Spill Trustee Council also requires a public advisory committee. The Public Advisory Committee was established to advise the Trustee Council, and began functioning in October 1992. The Public Advisory Committee consists of 15 members representing the following principal interests: Sport hunting and fishing, conservation and environmental, public-at-large, recreation users, commercial tourism, local government, science/technical, subsistence, commercial fishing, aquaculture and mariculture, regional monitoring programs, tribal government, marine transportation, and Native landowners.

In order to ensure that a broad range of public viewpoints continues to be available to the Trustee Council, and in keeping with the settlement agreement, the continuation of the Public Advisory Committee is recommended.

Certification

I hereby certify that the renewal of the Charter of the Public Advisory Committee is necessary and in the public interest in connection with the performance of duties mandated by the settlement of *United States* v. *State of Alaska,* No. A91–081 CV, and is in accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended and supplemented.

Dated: November 5, 2008.

Dirk Kempthorne,

Secretary of the Interior.

[FR Doc. E8–26827 Filed 11–10–08; 8:45 am]

BILLING CODE 4310–RG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–670–08–1610–DR]

Notice of Availability of Record of Decision for the Eastern San Diego County Resource Management Plan/ Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The BLM announces the availability of the Record of Decision (ROD)/Approved Resource Management Plan (RMP) for Eastern San Diego County. The California State Director signed the ROD on October 10, 2008, which constitutes the final decision of the BLM and makes the Approved RMP effective immediately.

ADDRESSES: Copies of the ROD/Approved RMP are available upon request from the Field Manager, El Centro Field Office, Bureau of Land Management, 1661 S. 4th Street, El Centro, CA 92243 or via the Internet at *http://www.ca.blm.gov/elcentro.* Copies of the ROD/Approved RMP can also be obtained from the BLM California State Office at 2800 Cottage Way, Suite W 1834, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Erin Dreyfuss, Eastern San Diego County RMP Team Leader, at (760) 337–4400, Bureau of Land Management, 1661 S. 4th Street, El Centro, CA 92243; *caesdrmp@ca.blm.gov.*

SUPPLEMENTARY INFORMATION: The planning area for the Eastern San Diego County RMP is the El Centro Field Office's area of management responsibility. Approximately 103,000 acres of public lands are administered by the BLM in the planning area. The decisions laid out in the ROD will apply only to BLM-administered lands and mineral estate in the planning area.

Planning for the RMP officially began with a **Federal Register** Notice on July 14, 2004 initiating the scoping process. The BLM sought participation from the public, tribes, and local, state, and federal agencies.

The RMP describes how the BLM intends to manage the planning area to meet desired resource conditions for vegetative communities, wildlife habitats, and cultural and visual resources. It also outlines management direction for recreation, protection of sensitive natural and cultural resources, energy and mineral development, land tenure adjustments and other planning issues raised during the planning process.

The BLM's Draft RMP/Draft Environmental Impact Statement (EIS) for the Eastern San Diego County Planning Area (February 2, 2007) presented alternatives to help the BLM and interested parties understand the various ways of addressing issues in the region. Upon evaluation of the alternatives and associated impacts described in the Draft RMP/EIS, and based on public and agency comments on that document, the BLM prepared the Proposed RMP and Final EIS (PRMP/FEIS) for Eastern San Diego County, which was released on December 7, 2007.

Nine protest letters on the PRMP/FEIS were received by the BLM. In response to these protests and based on additional policy discussions, the BLM decided to clarify and make changes to the Proposed Plan as set forth in the PRMP/FEIS, including: (1) Modifying renewable energy (wind) related proposals and (2) clarifying and modifying Visual Resource Management (VRM) proposals and classifications. On July 28, 2008, the BLM published a notice in the **Federal Register** to *Provide Opportunity to Comment on Changes to the Eastern San Diego County Proposed Resource Management Plan* for 30 calendar days.

After considering all of the protests on the PRMP/FEIS and the comments received on the proposed changes to the PRMP/FEIS, the BLM determined that the Preferred Alternative (Alternative E), as modified, best meets the purpose and need for the proposal.

The decisions designating routes of travel for motorized vehicles are implementation-level decisions and are

appealable under 43 CFR Part 4. These decisions are contained in Tables 2–19 and 2–20, and Map 2–20 of the Approved RMP. Any party adversely affected by the proposed route designations may appeal within 30 days of publication of this Notice of Availability. The appeal should state the specific route(s), as identified in the ROD/Approved RMP, on which the decision is being appealed. The appeal must be filed with the El Centro Field Manager at the above listed address.

Vicki L. Wood,

El Centro Field Manager.

[FR Doc. E8–26835 Filed 11–10–08; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

Final Environmental Impact Statement; General Management Plan; Olympic National Park, Clallam, Grays Harbor, Jefferson and Mason Counties, WA; Notice of Approval of Record of Decision

Summary: Pursuant to § 102(2)(C) of the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended) and the regulations promulgated by the Council on Environmental Quality (40 CFR 1505.2), the Department of the Interior, National Park Service has prepared and approved a Record of Decision (and Statement of Findings for Floodplains) for the Final Environmental Impact Statement (Final EIS) for General Management Plan (GMP) at Olympic National Park. The GMP will serve as a blueprint in guiding park management and research programs over the next 15–20 years. The requisite no-action ''wait period'' was initiated March 14, 2008, with the Environmental Protection Agency's **Federal Register** notification of the filing of the Final EIS.

Decision: As soon as practical Olympic National Park will begin to implement the restoration strategies, park operations, and visitor service projects identified and analyzed as the Preferred Alternative (Alternative D) contained in the Final EIS (and which included minor modifications from the course of action as presented in the Draft EIS (released for public review on June 15, 2006). The full range of foreseeable environmental consequences were assessed, and appropriate mitigation measures identified. Both a No Action alternative and two additional ''action'' alternatives were identified and analyzed. Alternative D was determined to be the ''environmentally preferred'' course of action.

Copies: Interested parties desiring to review the Record of Decision may obtain a copy by contacting the Superintendent, Olympic National Park, 600 East Park Ave., Port Angeles, WA 98362; or via telephone request at (360) 565–3000.

Dated: August 8, 2008.

Jonathan B. Jarvis,

Regional Director, Pacific West Region.

[FR Doc. E8–26728 Filed 11–10–08; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–659]

In the Matter of: Certain Prepregs, Laminates, and Finished Circuit Boards; Notice of Investigation

AGENCY: U.S. 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 October 6, 2008, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Isola USA Corp. of Chandler, Arizona. A supplement to the complaint was filed on October 28, 2008. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain prepregs, laminates, and finished circuit boards that infringe certain claims of U.S. Patent Nos. 6,187,852; 6,322,885 and 6,509,414. 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 an exclusion order and 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) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Juan Cockburn, Esq., 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 section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2008).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 5, 2008, 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 prepregs, laminates, or finished circuit boards that infringe one or more of claims 1–3, 5 and 8 of U.S. Patent No. 6,187,852; claims 1, 2, 4 and 7–9 of U.S. Patent No. 6,322,885; and claims 1 and 5–7 of U.S. Patent No. 6,509,414, 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—Isola USA Corp., 3100 W. Ray Road, Chandler, Arizona 85224.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

VENTEC Electronics (Suzhou) Co., Ltd., 168 Xiang Yang Road, Suzhou New District, Jiangsu 215009, China.

VENTEC Electronics (HK) Co., Ltd., Unit 311, 3/F, Block 2, Nan Fung Industrial City, 18 Tin Hua Road, Tuen Mun, New Territories, Hong Kong.

VGL USA LLC, 311 South Highland, Unit B, Fullerton, California 92832.

Taiwan Union Technology Corp., 803 Po Ai Street, Chupei City, Hsinchu 302, Taiwan.

ITEQ Corporation, 22, Kung Yeh 1st Road, Ping Cheng Industrial Zone, Ping Cheng Toayuan, Taiwan.

Guangdong Shengyi Sci. Tech Co., Ltd, No. 5 Western Industry Road, North Industry District, Songshan Lake SCI. & Tech. Industry Park, Dongguan City, Guangdong 523039, China.

Sanmina-SCI Corporation, 2700 North First Street, San Jose, California 95314.

(c) The Commission investigative attorney, party to this investigation, is Juan Cockburn, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401, Washington, DC 20436; and

(3) For the investigation so instituted, Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 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 not 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 and the notice of investigation 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 this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 5, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–26833 Filed 11–10–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–08–030]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 13, 2008 at 11 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436, *Telephone:* (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. No. 731–TA–1135 (Final) (Sodium Metal from France)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before November 24, 2008.)
5. Inv. Nos. 731–TA–986 and 987 (Review) (Ferrovanadium from China and South Africa)—briefing and vote. (The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before November 24, 2008.)
6. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 5, 2008.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E8–26763 Filed 11–10–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–08–031]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 14, 2008 at 11 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. No. 731–TA–752 (Second Review) (Crawfish Tail Meat from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before November 25, 2008.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 5, 2008.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E8–26764 Filed 11–10–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Three Consent Decrees Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on November 5, 2008, three proposed consent decrees in *United States* v. *Belle Tire Distr., Inc., et al.*, No. 06cv0816, were lodged with the United States District Court for the Western District of Michigan.

In this cost recovery action brought pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9607, the United States sought recovery of unreimbursed past response costs and prejudgment interest incurred by the United States Environmental Protection Agency for a removal action at the Carl's Tire Retreading Site near Grawn in Grand Traverse County, Michigan. Under the three proposed consent decrees, three defendants will pay a total of $97,000 to the Hazardous Substance Superfund, an amount determined based upon an analysis of their ability to pay a settlement or judgment.

The Department of Justice will accept comments relating to the three proposed consent decrees for a period of thirty (30) days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and mailed either electronically to *pubcomment-ees.enrd@usdoj.gov* or in hard copy to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611.

Comments should refer to *United States* v. *Belle Tire Distr., Inc., et al.*, Case No. 06cv0816 (W.D. Mich.) and D.J. Reference No. 90–11–3–09026.

The three proposed consent decrees may be examined at: (1) The Office of the United States Attorney for the Western District of Michigan, 330 Iona Avenue, Suite 501, Grand Rapids, Michigan 49503, (616) 456–2404; and (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact Steven P. Kaiser (312–353–3804)). During the comment period, the proposed consent decrees may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html*. Copies of the proposed consent decrees may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please refer to the referenced case and D.J. Reference No. 90–11–3–09026, and enclose a check in the amount of $13.50 for the three consent decrees (54 pages at 25 cents per page reproduction costs), made payable to the U.S. Treasury.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–26771 Filed 11–10–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act (CAA)

Notice is hereby given that on October 30, 2008, a proposed Consent Decree in *United States* v. *Biofriendly Corporation,* Civil Action No. CV08–7124 SJO (CTx), was lodged with the United States District Court for the Central District of California.

In this action, the United States sought civil penalties and injunctive relief under the Clean Air Act Section 211(d), 42 U.S.C. 7545(d), for violations of the statute's registration requirements pertaining to fuel additives and fuels containing additives, which are manufactured and sold in the United States. The proposed Consent Decree would require Biofriendly Corporation to pay a civil penalty to the United States in the amount of $1,250,000. Defendant's performance of obligations under the Consent Decree would resolve its liability for allegations in the underlying Complaint.

For a period of thirty (30) days from the date of this publication, the Department of Justice will receive comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov,* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. Comments should refer to *United States* v. *Biofriendly Corporation,* D.J. Ref. # 90–5–2–1–09094.

The proposed Consent Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the proposed Consent Decree also may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation no. (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $3.75 (25 cents per page reproduction cost) for a copy exclusive of signature pages and appendices, or $4.50 (25 cents per page reproduction cost) for a copy including signature pages and appendices payable to the ''U.S. Treasury'' or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section.

[FR Doc. E8–26735 Filed 11–10–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Oil Pollution Act

Notice is hereby given that on October 30, 2008, a proposed Consent Decree (''Decree'') in *United States et al.* v. *Enbridge Energy Limited Partnership,* Civil Action No. 0:08–cv–5878, was lodged with the United States District Court for the District of Minnesota.

In this action, the United States, the State of Minnesota, and the Leech Lake Band of Ojibwe sought to recover from Enbridge Energy Limited Partnership (''Enbridge'') natural resource damages under the Oil Pollution Act, 33 U.S.C. 2701, *et seq.*, and the Minnesota Water Pollution Control Act, Minn. Stat. § 115.071 subd.3, respectively, at the Enbridge Energy Site, Cohasset, Itasca County, MN, which arose from an alleged July 2002 discharge, from a subsurface pipeline owned by Enbridge, of 6,000 barrels of crude oil into a forested wetland within the watershed of a tributary of the Mississippi River.

Under the proposed Decree, Enbridge will: (i) Pay a total of $16,300 to the plaintiffs in reimbursement of the costs they incurred in assessing the natural resource damages (in addition to $112,000 in assessment costs previously reimbursed by Embridge); (ii) remove a portion of a forest road within the Chippewa National Forest; (iii) restore an impounded forested wetlands within the Chippewa National Forest; and (iv) retrofit, with diesel oxidation catalyst devices, ten diesel school buses owned by the Tribe.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States et al.* v. *Enbridge Energy Limited Partnership*, D.J. Ref. 90–5–1–1–08549.

The Decree may be examined at the Office of the United States Attorney, 300 S. 4th St., Suite 600, Minneapolis, MN 55415, and at U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, Illinois 60604. During the public comment period, the Decree may also be examined on the following Department of Justice Web site, to *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $34.35 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

William Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Verizon Communications Inc.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Verizon Communications Inc.,* Civil Action No. 08–cv–1878 (EGS). On October 30, 2008, the United States filed a Complaint alleging that the proposed acquisition by Verizon Communications Inc. of the wireless telecommunications services businesses of Alltel Corporation would violate Section 7 of the Clayton Act, 15 U.S.C. 18 by substantially lessening competition in the provision of mobile wireless telecommunications services in 94 cellular market areas (''CMAs''). The proposed Final Judgment, filed the same time as the Complaint, requires the divestiture of mobile wireless telecommunications services businesses for CMAs in the states of Alabama, Arizona, California, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, South Carolina, South Dakota, Utah, Virginia, and Wyoming.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 1st Floor, Liberty Square Building, 450 5th Street, Washington, DC 20530 (202–514–2481), on the Department of Justice's Web site (*http://www.usdoj.gov/atr*) and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee is set by the Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Nancy Goodman, Chief, Telecommunications and Media Enforcement Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 8000, Washington, DC 20530 (202–514–5621).

J. Robert Kramer II,

Director of Operations, Antitrust Division.

In the United States District Court for the District of Columbia

United States of America, Department of Justice, Antitrust Division, 1401 H Street, NW., Suite 8000, Washington, DC 20530;

State of Alabama, Attorney General, 500 Dexter Avenue, Montgomery, Alabama 36130;

State of California, California Office of the Attorney General, 300 So. Spring Street, Suite 1702, Los Angeles, California 90013;

State of Iowa, Iowa Department of Justice, Hoover Office Building-Second Floor, 1305 East Walnut Street, Des Moines, Iowa 50319;

State of Kansas, Kansas Office of the Attorney General, Consumer Protection/Antitrust, 120 SW 10th Avenue, 2nd Floor, Topeka, Kansas 66212;

State of Minnesota, Minnesota Attorney General's Office, 445 Minnesota Street, Suite 1200, St. Paul, Minnesota 55101;

State of North Dakota, Antitrust Division, Office of Attorney General, 4205 State Street, P.O. Box 1054, Bismarck, North Dakota 58502–1054;

and

State of South Dakota, Office of the Attorney General, 1302 E. Highway 14, Suite I, Pierre, South Dakota 57501–8501m

Plaintiffs,

v.

Verizon Communications Inc., 140 West Street, New York, New York 10007;

and

Alltel Corporation, One Allied Drive, Little Rock, Arkansas 72202,

Defendants.

Civil No. Case: 1:08–cv–01878. Assigned To: Sullivan, Emmet G. Assign. Date: 10/30/2008. Description: Antitrust.

Complaint

The United States of America, acting under the direction of the Attorney General of the United States, the State of Alabama, by its Attorney General Troy King, the State of California, by its Attorney General Edmund G. Brown Jr., the State of Iowa, by its Attorney General Thomas J. Miller, the State of Kansas, by its Attorney General Steve Six, the State of Minnesota, by its Attorney General Lori Swanson, the State of North Dakota, by its Attorney General Wayne Stenehjem, and the State of South Dakota, by its Attorney General Lawrence E. Long, bring this civil action to enjoin the merger of two mobile wireless telecommunications services providers, Verizon Communications Inc. (''Verizon'') and Alltel Corporation (''Alltel''), and to obtain other relief as appropriate. Plaintiffs allege as follows:

1. Verizon entered into an agreement to acquire Alltel, dated June 5, 2008, under which the two companies would combine their mobile wireless telecommunications services businesses (''Transaction Agreement''). Plaintiffs seek to enjoin this transaction because it likely will substantially lessen competition to provide mobile wireless telecommunications services in 94 geographic markets where Verizon and Alltel are among the most significant competitors.

2. Verizon's mobile wireless telecommunications services network covers 263 million people in 49 states and serves in excess of 70 million subscribers. Alltel provides mobile wireless telecommunications services in 35 states and serves approximately 13 million subscribers. The combination of Verizon and Alltel likely will substantially lessen competition for mobile wireless telecommunications services throughout North and South Dakota, and geographic areas in Alabama, Arizona, California, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, South Carolina, Utah, Virginia and Wyoming, where both Verizon and Alltel currently operate. As a result of the proposed acquisition, residents of these areas will likely face increased prices, diminished quality or quantity of services, and less investment in network improvements for these services.

I. Jurisdiction and Venue

3. This Complaint is filed by the United States under Section 15 of the Clayton Act, 15 U.S.C. 25, to prevent and restrain defendants from violating Section 7 of the Clayton Act, as amended, 15 U.S.C. 18. Plaintiffs Alabama, California, Iowa, Kansas, Minnesota, North Dakota, South Dakota by and through their respective Attorneys General, bring this action in their respective sovereign capacity and as parens patriae on behalf of the citizens, general welfare, and economy of their respective States under Section 16 of the Clayton Act, 15 U.S.C. 26, to prevent defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

4. Verizon and Alltel are engaged in interstate commerce and in activities substantially affecting interstate commerce. The Court has jurisdiction over this action pursuant to Sections 15

and 16 of the Clayton Act, 15 U.S.C. 25 and 26, and 28 U.S.C. 1331 and 1337.

5. The defendants have consented to personal jurisdiction and venue in this judicial district.

II. The Defendants and the Transaction

6. Verizon, with headquarters in New York, is a corporation organized and existing under the laws of the State of Delaware. Verizon is one of the world's largest providers of communications services. Verizon is the second largest mobile wireless telecommunications services provider in the United States as measured by subscribers, provides mobile wireless telecommunications services in 49 states, and serves in excess of 70 million subscribers. In 2007, Verizon earned mobile wireless telecommunications services revenues of approximately $43 billion.

7. Alltel, a subsidiary of Atlantis Holdings LLC, is a corporation organized and existing under the laws of the State of Delaware, with headquarters in Little Rock, Arkansas. Alltel is the fifth largest mobile wireless telecommunications services provider in the United States as measured by subscribers, and provides mobile wireless telecommunications services in 13 states. Alltel has approximately 13 million subscribers and in 2007, it earned approximately $8.8 billion in revenues.

8. Pursuant to the Transaction Agreement, Verizon will acquire Alltel for approximately $28 billion. If this transaction is consummated, Verizon and Alltel combined would have approximately 83 million subscribers in the United States, with over $51 billion in mobile wireless telecommunications services revenues.

III. Trade and Commerce

A. Nature of Trade and Commerce

9. Mobile wireless telecommunications services allow customers to make and receive telephone calls and obtain data services using radio transmissions without being confined to a small area during the call or data session, and without the need for unobstructed line-of-sight to the radio tower. Mobility is highly valued by customers, as demonstrated by the more than 262 million people in the United States who own mobile wireless telephones. In 2007, revenues from the sale of mobile wireless telecommunications services in the United States were over $138 billion. To meet this desire for mobility, mobile wireless telecommunications services providers must deploy extensive networks of switches, radio transmitters, and receivers and interconnect their networks with the networks of wireline carriers and other mobile wireless telecommunications services providers.

10. In the early to mid-1980s, the FCC issued two cellular licenses (A-block and B-block) in each Metropolitan Statistical Area (''MSA'') and Rural Service Area (''RSA'') (collectively, ''Cellular Market Areas'' or ''CMAs''), for a total of 734 CMAs covering the entire United States. Each license consists of 25 MHz of spectrum in the 800 MHz band. The first mobile wireless voice systems using this cellular spectrum were based on analog technology, now referred to as first-generation or ''IG'' technology.

11. In 1995, the FCC licensed additional spectrum for the provision of Personal Communications Services (''PCS''), a category of services that includes mobile wireless telecommunications services comparable to those offered by cellular licensees. These licenses are in the 1900 MHz band and are divided into six blocks: A, B, and C, which consist of 30 MHz each; and D, F, and F, which consist of 10 MHz each. Geographically, the A- and B-block 30 MHz licenses are issued by Major Trading Areas (''MTAs''). C-, D-, E-, and F-block licenses are issued by Basic Trading Areas (''BTAs''), several of which comprise each MTA. MTAs and BTAs do not generally correspond to MSAs and RSAs.

12. With the introduction of the PCS licenses, both cellular and PCS licensees began offering digital services, thereby increasing network capacity, shrinking the size of handsets, and extending handset battery life, in addition, in 1996, a specialized mobile radio (''SMR'' or ''dispatch'') spectrum licensee began using SMR spectrum to offer mobile wireless telecommunications services comparable to those offered by other mobile wireless telecommunications services providers, in conjunction with its dispatch, or ''push-to-talk,'' service. Although there are a number of providers holding spectrum licenses in each area of the country, not all providers have fully built out their networks throughout each license area. In particular, because of the characteristics of PCS spectrum, providers holding this type of spectrum generally have found it less attractive to build out in rural areas.

13. Today, more than 95 percent of the total U.S. population lives in counties where three or more mobile wireless telecommunications services operators offer service. Nearly all mobile wireless voice services have migrated to the second-generation, or ''2G'' digital technologies, using 3SM (global standard for mobility) or CDMA (code division multiple access). Even more advanced technologies (''2.5G'' and ''3G''), based on the earlier 2G technologies, have been deployed for mobile wireless data services.

B. Relevant Product Market

14. Mobile wireless telecommunications services is a relevant product market. Mobile wireless telecommunications services include both voice and data services provided over a radio network and allow customers to maintain their telephone calls or data sessions without wires when traveling. There are no cost-effective alternatives to mobile wireless telecommunications services. Because fixed wireless services are not mobile, they are not regarded by consumers of mobile wireless telecommunications services to be a reasonable substitute for those services. It is unlikely that a sufficient number of customers would switch away from mobile wireless telecommunications services to make a small but significant price increase in those services unprofitable. Mobile wireless telecommunications services accordingly is a relevant product market under Section 7 of the Clayton Act, 15 U.S.C. 18.

C. Relevant Geographic Markets

15. The United States comprises numerous local geographic markets for mobile wireless telecommunications services. A large majority of customers use mobile wireless telecommunications services in close proximity to their workplaces and homes. Thus, customers purchasing mobile wireless telecommunications services choose among mobile wireless telecommunications services providers that offer services where they live, work, and travel on a regular basis. The geographic areas in which the FCC has licensed mobile wireless telecommunications services providers often represent the core of the business and social sphere within which customers have the same competitive choices for mobile wireless telephone services. The number and identity of mobile wireless telecommunications services providers varies among geographic areas, as does the quality of services and breadth of geographic coverage offered by providers. Some mobile wireless telecommunications services providers can and do offer different promotions, discounts, calling plans, and equipment subsidies in different geographic areas, varying the price for customers by geographic area.

16. The relevant geographic markets, under Section 7 of the Clayton Act, 15 U.S.C. 18, where the transaction would substantially lessen competition for mobile wireless telecommunications services are effectively represented by the 94 FCC spectrum licensing areas specified in Appendix A. It is unlikely that a sufficient number of customers would switch to mobile wireless telecommunications services providers who do not offer services in these geographic areas to make a small but significant price increase in the relevant geographic markets unprofitable.

D. Anticompetitive Effects

1. Mobile Wireless Telecommunications Services

17. In each of the cellular license areas described in Appendix A, Verizon and Alltel are significant providers of mobile wireless telecommunications services (based on subscribers), and together their combined share in each area ranges from over 55% to 100%. In addition, each is the other's closest competitor for a significant set of customers.

18. The relevant geographic markets for mobile wireless services are highly concentrated. As measured by the Herfindahl-Hirschman Index (''HHI''), which is commonly employed in merger analysis and is defined and explained in Appendix B to this Complaint, concentration in these geographic areas ranges from over 2100 to more than 9100, which is well above the 1800 threshold at which plaintiffs consider a market to be highly concentrated. After Verizon's proposed acquisition of Alltel is consummated, the HHIs in the relevant geographic areas will range from over 4000 to 10,000, with increases in the HHI as a result of the merger ranging from over 300 to over 4900, significantly beyond the thresholds at which plaintiffs consider a transaction likely to cause competitive harm.

19. Competition between Verizon and Alltel in the relevant geographic markets has resulted in lower prices and higher quality in mobile wireless telecommunications services than otherwise would have existed in these geographic markets. In these areas, consumers consider Verizon and Alltel to be particularly attractive competitors because other providers' networks often lack coverage or provide lower-quality service, in all but two of these CMAs, Verizon and Alltel each hold cellular spectrum licenses. If Verizon's proposed acquisition of Alltel is consummated, competition between Verizon and Alltel in mobile wireless telecommunications services will be eliminated in these markets and the relevant markets for mobile wireless telecommunications services will become substantially more concentrated. As a result, the loss of competition between Verizon and Alltel increases the merged firm's incentive and ability in the relevant geographic markets to increase prices, diminish the quality or quantity of services provided, and refrain from or delay making investments in network improvements.

2. Entry

20. Entry by a new mobile wireless services provider in the relevant geographic markets would be difficult, time-consuming, and expensive, requiring spectrum licenses and the build out of a network. Therefore, any entry in response to a small but significant price increase for mobile wireless telecommunications services by the merged firm in the relevant geographic markets would not be timely, likely, or sufficient to thwart the competitive harm resulting from Verizon's proposed acquisition of Alltel, if it were consummated.

IV. Violation Alleged

21. The effect of Verizon's proposed acquisition of Alltel, if it were to be consummated, may be substantially to lessen competition in interstate trade and commerce in the relevant geographic markets for mobile wireless telecommunications services, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

22. Unless restrained, the transaction will likely have the following effects in mobile wireless telecommunications services in the relevant geographic markets, among others:

a. Actual and potential competition between Verizon and Alltel will be eliminated;

b. Competition in general will be lessened substantially;

c. Prices are likely to increase;

d. The quality and quantity of services are likely to decrease; and

e. Incentives to improve wireless networks will be reduced.

V. Requested Relief

The plaintiffs request:

23. That Verizon's proposed acquisition of Alltel be adjudged to violate Section 7 of the Clayton Act, 15 U.S.C. 18;

24. That defendants be permanently enjoined from and restrained from carrying out the Agreement and Plan of Merger dated June 5, 2008, or from entering into or carrying out any agreement, understanding, or plan, the effect of which would be to bring the wireless services businesses of Verizon and Alltel under common ownership or control;

25. That plaintiffs be awarded their costs of this action; and

26. That plaintiffs have such other relief as the Court may deem just and proper.

Dated: October 30, 2008

Respectfully Submitted,
FOR PLAINTIFF UNITED STATES OF AMERICA:

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Appendix A

(1) Lima OH MSA (CMA 158);
(2) Hickory NC MSA (CMA 166);
(3) Fargo-Moorhead ND-MN MSA (CMA 221);
(4) Mansfield OH MSA (CMA 231);
(5) Dothan AL MSA (CMA 246);
(6) Sioux City IA-NE MSA (CMA 253);
(7) Albany GA MSA (CMA 261);
(8) Danville VA MSA (CMA 262);
(9) Sioux Falls SD MSA (CMA 267);
(10) Billings MT MSA (CMA 268);
(11) Grand Forks ND-MN MSA (CMA 276);
(12) Rapid City SD MSA (CMA 289);
(13) Great Falls MT MSA (CMA 297);
(14) Bismarck ND MSA (CMA 298);
(15) Casper WY MSA (CMA 299);
(16) AL RSA 7 (CMA 313);
(17) AZ RSA 5 (CMA 322);
(18) CA RSA 6 (CMA 341);
(19) CO RSA 4 (CMA 351);
(20) CO RSA 5 (CMA 352);
(21) CO RSA 6 (CMA 353);
(22) CO RSA 7 (CMA 354);
(23) CO RSA 8 (CMA 355);
(24) CO RSA 9 (CMA 356);
(25) GA RSA 6 (CMA 376);
(26) GA RSA 7 (CMA 377);
(27) GA RSA 8 (CMA 378);
(28) GA RSA 9 (CMA 379);
(29) GA RSA 10 (CMA 380);
(30) GA RSA 12 (CMA 382);
(31) GA RSA 13 (CMA 383);
(32) ID RSA 2 (CMA 389);
(33) ID RSA 3 (CMA 390);
(34) IL RSA 8 (CMA 401);
(35) IL RSA 9 (CMA 402);
(36) IA RSA 8 (CMA 419);
(37) KS RSA 1 (CMA 428);
(38) KS RSA 2 (CMA 429);
(39) KS RSA 6 (CMA 433);
(40) KS RSA 7 (CMA 434);
(41) KS RSA 11 (CMA 438);
(42) KS RSA 12 (CMA 439);
(43) KS RSA 13 (CMA 440);
(44) MN RSA 1 (CMA 482);
(45) MN RSA 2 (CMA 483);
(46) MN RSA 7 (CMA 488);
(47) MT RSA 1 (CMA 523);
(48) MT RSA 2 (CMA 524);
(49) MT RSA 4 (CMA 526);
(50) MT RSA 5 (CMA 527);
(51) MT RSA 6 (CMA 528);
(52) MT RSA 7 (CMA 529);
(53) MT RSA 8 (CMA 530);
(54) MT RSA 9 (CMA 531);
(55) MT RSA 10 (CMA 532);
(56) NE RSA 5 (CMA 537);
(57) NV RSA 2 (CMA 544);
(58) NV RSA 5 (CMA 547);
(59) NM RSA 1 (CMA 553);
(60) NM RSA 5 (CMA 557);
(61) NM RSA 6 (CMA 558);
(62) NC RSA 2 (CMA 566);
(63) NC RSA 5 (CMA 569);
(64) NT RSA 1 (CMA 580);
(65) ND RSA 2 (CMA 581);
(66) ND RSA 3 (CMA 582);
(67) ND RSA 4 (CMA 583);
(68) ND RSA 5 (CMA 584);
(69) OH RSA 2 (CMA 586);
(70) OH RSA 5 (CMA 589);
(71) OH RSA 6 (CMA 590);
(72) SC RSA 1 (CMA 625);
(73) SC RSA 2 (CMA 626);
(74) SC RSA 3 (CMA 627);
(75) SC RSA 7 (CMA 631);
(76) SD RSA 1 (CMA 634);
(77) SD RSA 2 (CMA 635);
(78) SD RSA 3 (CMA 636);
(79) SD RSA 4 (CMA 637);
(80) SD RSA 5 (CMA 638);
(81) SD RSA 6 (CMA 639);
(82) SD RSA 7 (CMA 640);
(83) SD RSA 8 (CMA 641);
(84) SD RSA 9 (CMA 642);
(85) UT RSA 3 (CMA 675);
(86) UT RSA 4 (CMA 676);
(87) UT RSA 5 (CMA 677);
(88) UT RSA 6 (CMA 678);
(89) VA RSA 1 (CMA 681);
(90) VA RSA 8 (CMA 688);
(91) WY RSA 1 (CMA 718);
(92) WY RSA 2 (CMA 719);
(93) WY RSA 4 (CMA 721);
(94) WY RSA 5 (CMA 722).

Appendix B

Herfindahl-Hirschman Index

''HHI'' means the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2600 ($30^2 + 30^2 + 20^2 + 20^2 = 2600$). (**Note:** Throughout the Complaint, market share percentages have been rounded to the nearest whole number, but HHIs have been estimated using unrounded percentages in order to accurately reflect the concentration of the various markets.) The HHI takes into account the relative size distribution of the firms in a market and approaches zero when a market consists of a large number of small firms. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

Markets in which the HHI is between 1000 and 1800 points are considered to be moderately concentrated, and those in which the HHI is in excess of 1800 points are considered to be highly concentrated. *See Horizontal Merger Guidelines* ¶ 1.51 (revised Apr. 8, 1997). Transactions that increase the HHI by more than 100 points in concentrated markets presumptively raise antitrust concerns under the guidelines issued by the U.S. Department of Justice and Federal Trade Commission. *See id.*

In the United States District Court for the District of Columbia United States of America, State of Alabama, State of California, State of Iowa, State of Kansas, State of Minnesota, State of North Dakota, and State of South Dakota:

Plaintiffs,

v.

Verizon Communications Inc., and Alltel Corporation,

Defendants.

Civil No.: 08 1878.

Final Judgment

Whereas, plaintiffs, United States of America, State of Alabama, State of California, State of Iowa, State of Kansas, State of Minnesota, State of North Dakota, and State of South Dakota, filed their Complaint on October, 2008, plaintiffs and defendants, Verizon Communications Inc. (''Verizon'') and Alltel Corporation (''Alltel''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

And whereas, defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by defendants to assure that competition is not substantially lessened;

And whereas, plaintiffs require defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, defendants have represented to plaintiffs that the divestitures required below can and will be made and that defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Acquirer'' or ''Acquirers'' means the entity or entities to whom defendants divest the Divestiture Assets.

B. ''Alltel'' means Alltel Corporation, a subsidiary of Atlantis Holdings LLC, a corporation organized and existing under the laws of the State of Delaware, with headquarters in Little Rock, Arkansas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''CMA'' means cellular market area which is used by the Federal Communications Commission (''FCC'') to define cellular license areas and which consists of Metropolitan Statistical Areas (''MSAs'') and Rural Service Areas (''RSAs'').

D. ''Divestiture Assets'' means each mobile wireless telecommunications services business to be divested under this Final Judgment, including all types of assets, tangible and intangible, used by defendants in the operation of the mobile wireless telecommunications services businesses to be divested. To ensure that the divested mobile wireless telecommunications services businesses remain viable, ongoing businesses, the term ''Divestiture Assets'' shall be construed broadly to accomplish the complete divestiture, as required by this Final Judgment, of the entire business of

(1) Alltel in each of the following CMA license areas:

(a) Lima OH MSA (CMA 158);
(b) Hickory NC MSA (CMA 166);
(c) Fargo-Moorhead ND-MN MSA (CMA 221);
(d) Mansfield OH MSA (CMA 231);
(e) Dothan AL MSA (CMA 246);
(f) Sioux City IA-NE MSA (CMA 253);
(g) Albany GA MSA (CMA 261);
(h) Danville VA MSA (CMA 262);
(i) Sioux Falls SD MSA (CMA 267);
(j) Billings MT MSA (CMA 268);
(k) Grand Forks ND-MN MSA (CMA 276);
(l) Rapid City SD MSA (CMA 289);
(m) Great Falls MT MSA (CMA 297);
(n) Bismarck ND MSA (CMA 298);
(o) Casper WY MSA (CMA 299);
(p) AL RSA 7 (CMA 313);
(q) AZ RSA 5 (CMA 322);
(r) CA RSA 6 (CMA 341);
(s) CO RSA 4 (CMA 351);
(t) CO RSA 5 (CMA 352);
(u) CO RSA 6 (CMA 353);
(v) CO RSA 7 (CMA 354);
(w) CO RSA 8 (CMA 355);
(x) CO RSA 9 (CMA 356);
(y) GA RSA 6 (CMA 376);
(z) GA RSA 7 (CMA 377);
(aa) GA RSA 8 (CMA 378);
(bb) GA RSA 9 (CMA 379);
(cc) GA RSA 10 (CMA 380);
(dd) GA RSA 12 (CMA 382);
(ee) GA RSA 13 (CMA 383);
(ff) ID RSA 2 (CMA 389);
(gg) ID RSA 3 (CMA 390);
(hh) IL RSA 8 (CMA 401);
(ii) IL RSA 9 (CMA 402);
(jj) IA RSA 8 (CMA 419);
(kk) MN RSA 1 (CMA 482);
(ll) MN RSA 2 (CMA 483);
(mm) MT RSA 1 (CMA 523);
(nn) MT RSA 2 (CMA 524);
(oo) MT RSA 4 (CMA 526);
(pp) MT RSA 5 (CMA 527);
(qq) MT RSA 6 (CMA 528);
(rr) MT RSA 7 (CMA 529);
(ss) MT RSA 8 (CMA 530);
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(yy) NM RSA 5 (CMA 557);
(zz) NM RSA 6 (CMA 558);
(aaa) NC RSA 2 (CMA 566);
(bbb) NC RSA 5 (CMA 569);
(ccc) ND RSA 1 (CMA 580);
(ddd) ND RSA 2 (CMA 581);
(eee) ND RSA 3 (CMA 582);
(fff) ND RSA 4 (CMA 583);
(ggg) ND RSA 5 (CMA 584);
(hhh) OH RSA 2 (CMA 586);
(iii) OH RSA 5 (CMA 589);
(jjj) OH RSA 6 (CMA 590);
(kkk) SC RSA 1 (CMA 625);
(lll) SC RSA 2 (CMA 626);
(mmm) SC RSA 3 (CMA 627);
(nnn) SC RSA 7 (CMA 631);
(ooo) SD RSA 1 (CMA 634);
(ppp) SD RSA 2 (CMA 635);
(qqq) SD RSA 3 (CMA 636);
(rrr) SD RSA 4 (CMA 637);
(sss) SD RSA 5 (CMA 638);
(ttt) SD RSA 6 (CMA 639);
(uuu) SD RSA 7 (CMA 640);
(vvv) SD RSA 8 (CMA 641);
(www) SD RSA 9 (CMA 642);
(xxx) UT RSA 3 (CMA 675);
(yyy) UT RSA 4 (CMA 676);
(zzz) UT RSA 5 (CMA 677);
(aaaa) UT RSA 6 (CMA 678);
(bbbb) VA RSA 1 (CMA 681);
(cccc) VA RSA 8 (CMA 688);
(dddd) WY RSA 1 (CMA 718);
(eeee) WY RSA 2 (CMA 719);
(ffff) WY RSA 4 (CMA 721);
(gggg) WY RSA 5 (CMA 722).

(2) Verizon, that was acquired from Rural Cellular Corporation in August 2008, in each of the following CMA license areas:

(a) KS RSA 1 (CMA 428);
(b) KS RSA 2 (CMA 429);
(c) KS RSA 6 (CMA 433);
(d) KS RSA 7 (CMA 434);
(e) KS RSA 11 (CMA 438);
(f) KS RSA 12 (CMA 439);
(g) KS RSA 13 (CMA 440); and

(3) Verizon (but not including any assets acquired from Rural Cellular Corporation) in each of the following CMA license areas:

(a) MN RSA 7 (CMA 488); and
(b) NE RSA 5 (CMA 537).

The Divestiture Assets shall include, without limitation, all types of real and personal property, monies and financial instruments, equipment, inventory,

office furniture, fixed assets and furnishings, supplies and materials, contracts, agreements, leases, commitments, spectrum licenses issued by the FCC and all other licenses, permits and authorizations, operational support systems, cell sites, network infrastructure, switches, customer support and billing systems, interfaces with other service providers, business and customer records and information, customer contracts, customer lists, credit records, accounts, and historic and current business plans that relate primarily to the wireless businesses being divested, as well as any patents, licenses, sublicenses, trade secrets, know-how, drawings, blueprints, designs, technical and quality specifications and protocols, quality assurance and control procedures, manuals and other technical information defendants supply to their own employees, customers, suppliers, agents, or licensees, and trademarks, trade names and service marks or other intellectual property, including all intellectual property rights under third-party licenses that are capable of being transferred to the Acquirer(s) either in their entirety, for assets described in (a) below, or through a license obtained through or from defendants, for assets described in (b) below; provided that defendants shall only be required to divest Multi-line Business Customer contracts if the primary business address for that customer is located within any of the license areas described herein, and further, any subscriber who obtains mobile wireless telecommunications services through any such contract retained by defendants and who are located within the license areas identified above, shall be given the option to terminate their relationship with defendants, without financial cost, at any time within one year of the closing of the Transaction. Defendants shall provide written notice to these subscribers within 45 days after the closing of the Transaction of the option to terminate.

The divestiture of the Divestiture Assets shall be accomplished by:

(a) transferring to the Acquirer(s) the complete ownership and/or other rights to the assets (other than those assets used substantially in the operations of defendants' overall wireless telecommunications services business that must be retained to continue the existing operations of the wireless properties that defendants are not required to divest, and that either are not capable of being divided between the divested wireless telecommunications services businesses and those not divested, or are assets that the defendants and the Acquirer(s) agree, subject to the approval of plaintiff United States, shall not be divided); and

(b) granting to the Acquirer(s) an option to obtain a nonexclusive, transferable license from defendants for a reasonable period, subject to the approval of plaintiff United States, and at the election of the Acquirer(s), to use any of defendants' retained assets under paragraph (a) above used in operating the mobile wireless telecommunications services businesses being divested, so as to enable the Acquirer(s) to continue to operate the divested mobile wireless telecommunications services businesses without impairment. Defendants shall identify in a schedule submitted to plaintiff United States and filed with the Court as expeditiously as possible following the filing of the Complaint, and in any event prior to any divestiture and before the approval by the Court of this Final Judgment, any and all intellectual property rights under third-party licenses that are used by the mobile wireless telecommunications services businesses being divested that defendants could not transfer to the Acquirer(s) entirely or by license without third-party consent, the specific reasons why such consent is necessary, and how such consent would be obtained for each asset.

E. ''Multi-line Business Customer'' means a corporate or business customer that contracts with a divesting defendant for mobile wireless telecommunications services to provide multiple telephones to its employees or members whose services are provided pursuant to a contract with the corporate or business customer.

F. ''Transaction'' means the Agreement and Plan of Merger among Ceilco Partnership, Airtouch Cellular, Abraham Merger Corporation, Alltel Corporation and Atlantis Holdings LLC, dated June 5, 2008.

G. ''Verizon'' means defendant Verizon Communications Inc., a Delaware corporation, with its headquarters in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

III. Applicability

A. This Final Judgment applies to defendants Verizon and Alltel, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with Section IV and V of this Final Judgment, defendants sell or otherwise dispose of all or substantially all of their assets or of lesser business units that include the Divestiture Assets, they shall require the purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from the acquirer(s) of the assets divested pursuant to this Final Judgment.

IV. Divestitures

A. Defendants are ordered and directed, within 120 days after consummation of the Transaction, or five calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Assets in a manner consistent with this Final Judgment to an Acquirer or Acquirers acceptable to plaintiff United States in its sole discretion, upon consultation with the relevant plaintiff State, or, if applicable, to a Divestiture Trustee designated pursuant to Section V of this Final Judgment. Plaintiff United States, in its sole discretion, upon consultation with the relevant plaintiff State, may agree to one or more extensions of this time period not to exceed 60 calendar days in total, and shall notify the Court in such circumstances. With respect to divestiture of the Divestiture Assets by defendants or the Divestiture Trustee, if applications have been filed or are on file with the FCC within the period permitted for divestiture seeking approval to assign or transfer licenses to the Acquirer(s) of the Divestiture Assets, but an order or other dispositive action by the FCC on such applications has not been issued before the end of the period permitted for divestiture, the period shall be extended with respect to divestiture of those Divestiture Assets for which FCC approval has not been issued until five days after such approval is received. Defendants agree to use their best efforts to accomplish the divestitures set forth in this Final Judgment and to seek all necessary regulatory approvals as expeditiously as possible. This Final Judgment does not limit the FCC's exercise of its regulatory powers and process with respect to the Divestiture Assets. Authorization by the FCC to conduct the divestiture of a Divestiture Asset in a particular manner will not modify any of the requirements of this decree.

B. In accomplishing the divestitures ordered by this Final Judgment, defendants shall promptly make known, if they have not already done so, by usual and customary means, the availability of the Divestiture Assets. Defendants shall inform any person making inquiry regarding a possible purchase of the Divestiture Assets that

they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment. Defendants shall offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process except such information or documents subject to the attorney-client or work product privileges. Defendants shall make available such information to plaintiffs at the same time that such information is made available to any other person.

C. Defendants shall provide the Acquirer(s) and plaintiffs information relating to the personnel involved in the operation, development, and sale or license of the Divestiture Assets to enable the Acquirer(s) to make offers of employment. Defendants will not interfere with any negotiations by the Acquirer(s) to employ any defendant employee whose primary responsibility is the operation, development, or sale or license of the Divestiture Assets.

D. Defendants shall permit prospective Acquirers of the Divestiture Assets to have reasonable access to personnel and to make inspections of the Divestiture Assets; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, and other documents and information customarily provided as part of a due diligence process.

E. Defendants shall warrant to the Acquirer(s) that (1) the Divestiture Assets will be operational on the date of sale, and (2) every wireless spectrum license is in full force and effect on the date of sale.

F. Defendants shall not take any action that will impede in any way the permitting, licensing, operation, or divestiture of the Divestiture Assets.

G. Defendants shall warrant to the Acquirer(s) of the Divestiture Assets that there are no material defects in the environmental, zoning, licensing or other permits pertaining to the operation of each asset and that following the sale of the Divestiture Assets, defendants will not undertake, directly or indirectly, any challenges to the environmental, zoning, licensing or other permits relating to the operation of the Divestiture Assets.

H. Unless plaintiff United States, in its sole discretion upon consultation with the relevant plaintiff State, otherwise consents in writing, the divestitures pursuant to Section IV, or by a Divestiture Trustee appointed pursuant to Section V, of this Final Judgment, shall include the entire Divestiture Assets, and shall be accomplished in such a way as to satisfy plaintiff United States in its sole discretion that these assets can and will be used by the Acquirer(s) as part of a viable, ongoing business engaged in the provision of mobile wireless telecommunications services. The divestiture of the Divestiture Assets, whether pursuant to Section IV or Section V of this Final Judgment:

(1) shall be made to an Acquirer or Acquirers that, in plaintiff United States's sole judgment, upon consultation with the relevant plaintiff State, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the provision of mobile wireless telecommunications services; and

(2) shall be accomplished so as to satisfy plaintiff United States in its sole discretion, upon consultation with the relevant plaintiff State, that none of the terms of any agreement between an Acquirer(s) and defendants shall give defendants the ability unreasonably to raise the Acquirer's costs, to lower the Acquirer's efficiency, or otherwise to interfere with the ability of the Acquirer to compete effectively.

I. The Divestiture Assets listed in each numbered subsection below shall be divested together to a single Acquirer, provided that it is demonstrated to the sole satisfaction of plaintiff United States, upon consultation with the relevant plaintiff State, that the Divestiture Assets will remain viable and the divestiture of such assets will remedy the competitive harm alleged in the Complaint:

(1) Alabama
(a) Dothan MSA (CMA 246);
(b) ALRSA7 (CMA 313);

(2) Colorado
(a) CO RSA 4 (CMA 351);
(b) CO RSA 5 (CMA 352);
(c) CO RSA 6 (CMA 353);
(d) CO RSA 7 (CMA 354);
(e) CO RSA 8 (CMA 355);
(f) CO RSA 9 (CMA 356);

(3) Georgia
(a) Albany MSA (CMA 261);
(b) GA RSA 6 (CMA 376);
(c) GA RSA 7 (CMA 377);
(d) GA RSA 8 (CMA 378);
(e) GA RSA 9 (CMA 379);
(f) GA RSA 10 (CMA 380);
(g) GA RSA 12 (CMA 382);
(h) GA RSA 13 (CMA 383);

(4) Idaho
(a) ID RSA2 (CMA 389);
(b) ID RSA 3 (CMA 390);

(5) Illinois
(a) IL RSA 8 (CMA 401);
(b) IL RSA 9 (CMA 402);

(6) Iowa/Nebraska
(a) Sioux City MSA (CMA 253);
(b) IA RSA 8 (CMA 419);
(c) NE RSA 5 (CMA 537);

(7) Kansas
(a) KS RSA 1 (CMA 428);
(b) KS RSA 2 (CMA 429);
(c) KS RSA 6 (CMA 433);
(d) KS RSA 7 (CMA 434);
(e) KS RSA 11 (CMA 438);
(f) KS RSA 12 (CMA 439);
(g) KS RSA 13 (CMA 440);

(8) Southern Minnesota
(a) MN RSA 7 (CMA 488);

(9) Montana
(a) Billings MSA (CMA 268);
(b) Great Falls MSA (CMA 297);
(c) MT RSA 1 (CMA 523);
(d) MT RSA 2 (CMA 524);
(e) MT RSA 4 (CMA 526);
(f) MT RSA 5 (CMA 527);
(g) MT RSA 6 (CMA 528);
(h) MT RSA 7 (CMA 529);
(i) MT RSA 8 (CMA 530);
(j) MT RSA 9 (CMA 531);
(k) MT RSA 10 (CMA 532);

(10) Nevada
(a) NV RSA 2 (CMA 544);
(b) NV RSA 5 (CMA 547);

(11) New Mexico
(a) NM RSA 5 (CMA 557);
(b) NM RSA 6 (CMA 558);

(12) North Carolina
(a) Hickory MSA (CMA 166);
(b) NC RSA 2 (CMA 566);
(c) NC RSA 5 (CMA 569);

(13) North Dakota/Northern Minnesota
(a) Fargo-Moorhead ND-MN MSA (CMA 221);
(b) Grand Forks ND-MN MSA (CMA 276);
(c) Bismarck MSA (CMA 298);
(d) MN RSA 1 (CMA 482);
(e) MN RSA 2 (CMA 483);
(f) ND RSA 1 (CMA 580);
(g) ND RSA 2 (CMA 581);
(h) ND RSA 3 (CMA 582);
(i) ND RSA 4 (CMA 583);
(j) ND RSA 5 (CMA 584);

(14) Ohio
(a) Lima MSA (CMA 158);
(b) Mansfield MSA (CMA 231);
(c) OH RSA 2 (CMA 586);
(d) OH RSA 5 (CMA 589);
(e) OH RSA 6 (CMA 590);

(15) South Carolina
(a) SC RSA 1 (CMA 625);
(b) SC RSA 2 (CMA 626);
(c) SC RSA 3 (CMA 627);
(d) SC RSA 7 (CMA 631);

(16) South Dakota
(a) Sioux Falls MSA (CMA 267);
(b) Rapid City MSA (CMA 289);
(c) SD RSA 1 (CMA 634);
(d) SD RSA 2 (CMA 635);
(e) SD RSA 3 (CMA 636);

(f) SD RSA 4 (CMA 637);
(g) SD RSA 5 (CMA 638);
(h) SD RSA 6 (CMA 639);
(i) SD RSA 7 (CMA 640);
(j) SD RSA 8 (CMA 641);
(k) SD RSA 9 (CMA 642);

(17) Utah
(a) UT RSA 3 (CMA 675);
(b) UT RSA 4 (CMA 676);
(c) UT RSA 5 (CMA 677);
(d) UT RSA 6 (CMA 678);

(18) Wyoming
(a) Casper MSA (CMA 299);
(b) WY RSA 1 (CMA 718);
(c) WY RSA 2 (CMA 7I9);
(d) WY RSA 4 (CMA 721);
(e) WY RSA 5 (CMA 722);

provided however: (i) The Divestiture Assets in Minnesota RSA 7 must be divested to the same acquirer as the wireless business assets in Minnesota RSA 7 (CMA 488), Minnesota RSA 8 (CMA 489), Minnesota RSA 9 (CMA 490) and Minnesota RSA 10 (CMA 491), recently purchased by defendant Verizon from Rural Cellular Corporation, that must be divested pursuant to the proposed Modified Final Judgment in *United Slates et al.* v. *ALLTEL Corp. et al.*, Civ. No. 06–363 1 (RHKJAJB) (D. MN filed Sept. 7, 2006); (ii) the Divestiture Assets in New Mexico RSAs 5 and 6 must be divested to the same acquirer as the wireless business assets in the Las Cruces NM MSA (CMA 285), currently owned by defendant Alltel, that must be divested pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al,* Civ. No. 1 :99C Vol 119 (EGS) (D.D.C. filed May 7, 1999); (iii) the Divestiture Assets in the Lima and Mansfield OH MSAs and OH RSAs 2, 5 and 6 must be divested to the same acquirer as the wireless business assets in the OH RSA 3 (CMA 587), currently owned by defendant Alltel, that must be divested pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. 1:99C Vol 119 (EGS) (D.D.C. May 7, 1999); and (iv) the Divestiture Assets in SC RSAs 1, 2, 3 and 7 must be divested to the same acquirer as the wireless business assets in the Anderson SC MSA (CMA 227), currently owned by defendant Alltel, that must be divested pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. I :99CV01 119 (EGS) (D.D.C. May 7, 1999). In addition to the foregoing, nothing in this section shall be construed as limiting the ability of an Acquirer to purchase the assets in more than one numbered subsection, and defendants shall be required to consider bids from potential acquirers that are contingent on the acquisition of all of the assets in more than one of the numbered subsections. The assets in each CMA license area listed in Subsection II.D of this Final Judgment but not listed in any of the above subsections (Danville VA MSA (CMA 262); AZ RSA 5 (CMA 322); CA RSA 6 (CMA 341); NM RSA 1 (CMA 553); VA RSA 1 (CMA 681); and VA RSA 8 (CMA 688)) can be sold to a single Acquirer or acquired together with other Divestiture Assets. With the written approval of plaintiff United States, in its sole discretion, upon consultation with the relevant plaintiff State, defendants or the Divestiture Trustee may sell, to a single acquirer, fewer than all of the assets contained in the numbered subsections above, to facilitate prompt divestiture to an acceptable Acquirer(s).

J. At the option of the Acquirer(s) of the Divestiture Assets, defendants shall enter into a contract for transition services customarily provided in connection with the sale of a business providing mobile wireless telecommunications services or intellectual property licensing sufficient to meet all or part of the needs of the Acquirer(s) for a period of up to one year, provided that defendants shall only be required to license the Verizon brand to the acquirer(s) of the Divestiture Assets in the CMAs listed in Section ILD.3 for a period of nine (9) months. The terms and conditions of any contractual arrangement meant to satisl3 this provision must be reasonably related to market conditions.

K. To the extent that the Divestiture Assets use intellectual property, as required to be identified by Section HD, that cannot be transferred or assigned without the consent of the licensor or other third parties, defendants shall use their best efforts to obtain those consents.

V. Appointment of Divestiture Trustee

A. If defendants have not divested the Divestiture Assets within the time period specified in Section IV.A, defendants shall notify plaintiff United States, and the relevant plaintiff State of that fact in writing, specifically identifying the Divestiture Assets that have not been divested. Upon application of plaintiff United States, upon consultation with the relevant plaintiff State, the Court shall appoint a Divestiture Trustee selected by plaintiff United States and approved by the Court to effect the divestiture of the Divestiture Assets. The Divestiture Trustee will have all the rights and responsibilities of the Management Trustee who may be appointed pursuant to the Preservation of Assets Stipulation and Order, and will be responsible for:

(1) Accomplishing divestiture of all Divestiture Assets transferred to the Divestiture Trustee from defendants, in accordance with the terms of this Final Judgment, to an Acquirer(s) approved by plaintiff United States, in its sole discretion upon consultation with the relevant plaintiff State, under Section IV.A of this Final Judgment; and

(2) Exercising the responsibilities of the licensee of any transferred Divestiture Assets and controlling and operating any transferred Divestiture Assets, to ensure that the businesses remain ongoing, economically viable competitors in the provision of mobile wireless telecommunications services in the license areas specified in Section II.D, until they are divested to an Acquirer(s), and the Divestiture Trustee shall agree to be bound by this Final Judgment.

B. Defendants shall submit a proposed trust agreement (''Trust Agreement'') to plaintiff United States, which must be consistent with the terms of this Final Judgment and which must receive approval by plaintiff United States in its sole discretion, upon consultation with the relevant plaintiff State, who shall communicate to defendants within 10 business days its approval or disapproval of the proposed Trust Agreement, and which must be executed by the defendants and the Divestiture Trustee within five business days after approval by plaintiff United States.

C. After obtaining any necessary approvals from the FCC for the assignment of the licenses of the Divestiture Assets to the Divestiture Trustee, defendants shall irrevocably divest the remaining Divestiture Assets to the Divestiture Trustee, who will own such assets (or own the stock of the entity owning such assets, if divestiture is to be effected by the creation of such an entity for sale to Acquirer) and control such assets, subject to the terms of the approved Trust Agreement.

D. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right to sell the Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestiture to an Acquirer(s) acceptable to plaintiff United States, in its sole judgment, upon consultation with the relevant plaintiff State, at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and shall have such other powers as this Court deems

appropriate. Subject to Section V.G of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of defendants the Management Trustee appointed pursuant to the Preservation of Assets Stipulation and Order and any investment bankers, attorneys or other agents, who shall be solely accountable to the Divestiture Trustee, reasonably necessary in the Divestiture Trustee's judgment to assist in the divestiture.

E. In addition, notwithstanding any provision to the contrary, plaintiff United States, in its sole discretion, upon consultation with the relevant plaintiff State, may (1) require defendants to include additional assets, and (2) with the written approval of plaintiff United States, allow defendants to substitute substantially similar assets, which substantially relate to the Divestiture Assets to be divested by the Divestiture Trustee.

F. Defendants shall not object to a sale by the Divestiture Trustee on any ground other than the Divestiture Trustee's malfeasance. Any such objections by defendants must be conveyed in writing to plaintiff United States and the Divestiture Trustee within 10 calendar days after the Divestiture Trustee has provided the notice required under Section VI.

G. The Divestiture Trustee shall serve at the cost and expense of defendants, on such terms and conditions as plaintiff United States approves, and shall account for all monies derived from the sale of the assets sold by the Divestiture Trustee and all costs and expenses so incurred. After approval by the Court of the Divestiture Trustee's accounting, including fees for its services and those of any professionals and agents retained by the Divestiture Trustee, all remaining money shall be paid to defendants and the trust shall then be terminated. The compensation of the Divestiture Trustee and any professionals and agents retained by the Divestiture Trustee shall be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement providing the Divestiture Trustee with an incentive based on the price and terms of the divestiture, and the speed with which it is accomplished, but timeliness is paramount.

H. Defendants shall use their best efforts to assist the Divestiture Trustee in accomplishing the required divestitures, including their best efforts to effect all necessary regulatory approvals. The Divestiture Trustee and any consultants, accountants, attorneys, and other persons retained by the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities of the businesses to be divested, and defendants shall develop financial and other information relevant to the assets to be divested as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information. Defendants shall take no action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestitures.

I. After its appointment, the Divestiture Trustee shall file monthly reports with plaintiff United States, and the relevant plaintiff States, and the Court setting forth the Divestiture Trustee's efforts to accomplish the divestitures ordered under this Final Judgment. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the (1) investiture Assets.

J. If the Divestiture Trustee has not accomplished the divestitures ordered under the Final Judgment within six months after its appointment, the Divestiture Trustee shall promptly file with the Court a report setting forth (1) The Divestiture Trustee's efforts to accomplish the required divestitures, (2) the reasons, in the Divestiture Trustee's judgment, why the required divestitures have not been accomplished, and (3) the Divestiture Trustee's recommendations. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. The Divestiture Trustee shall at the same time furnish such report to plaintiff United States, and the relevant plaintiff States, who shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by plaintiff United States, upon consultation with the relevant plaintiff States.

K. After defendants transfer the Divestiture Assets to the Divestiture Trustee, and until those Divestiture Assets have been divested to an Acquirer or Acquirers approved by plaintiff United States pursuant to Sections IV.A and IVU, the Divestiture Trustee shall have sole and complete authority to manage and operate the Divestiture Assets and to exercise the responsibilities of the licensee and shall not be subject to any control or direction by defendants. Defendants shall not use, or retain any economic interest in, the Divestiture Assets transferred to the Divestiture Trustee, apart from the right to receive the proceeds of the sale or other disposition of the Divestiture Assets.

L. The Divestiture Trustee shall operate the Divestiture Assets consistent with the Preservation of Assets Stipulation and Order and this Final Judgment, with control over operations, marketing, and sales. Defendants shall not attempt to influence the business decisions of the Divestiture Trustee concerning the operation and management of the Divestiture Assets, and shall not communicate with the Divestiture Trustee concerning divestiture of the Divestiture Assets or take any action to influence, interfere with, or impede the Divestiture Trustee's accomplishment of the divestitures required by this Final Judgment, except that defendants may communicate with the Divestiture Trustee to the extent necessary for defendants to comply with this Final Judgment and to provide the Divestiture Trustee, if requested to do so, with whatever resources or cooperation may be required to complete divestiture of the Divestiture Assets and to carry out the requirements of the Preservation of Assets Stipulation and Order and this Final Judgment. Except as provided in this Final Judgment and the Preservation of Assets Stipulation and Order, in no event shall defendants provide to, or receive from, the Divestiture Trustee or the mobile wireless telecommunications services businesses any non public or competitively sensitive marketing, sales, pricing or other information relating to their respective mobile wireless telecommunications services businesses.

VI. Notice of Proposed Divestitures

A. Within the later of two (2) business days following (i) the execution of a definitive divestiture agreement, or (ii) the filing of the Complaint in this action, defendants or the Divestiture Trustee, whichever is then responsible for effecting the divestitures required herein, shall notify plaintiff United States, and the relevant plaintiff State,

in writing of any proposed divestiture required by Section IV or V of this Final Judgment. If the Divestiture Trustee is responsible, it shall similarly notify defendants. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with fill details of the same.

B. Within fifteen (15) calendar days of receipt of notice by plaintiff United States and the relevant plaintiff State, plaintiff United States and any plaintiff State receiving such notice, may request from defendants, the proposed Acquirer, any other third party, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer, and any other potential Acquirer. Defendants and the Divestiture Trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice or within twenty (20) calendar days after plaintiff United States and the relevant plaintiff State have been provided the additional information requested from defendants, the proposed Acquirer, any third party, and the Divestiture Trustee, whichever is later, plaintiff United Slates, upon consultation with the relevant plaintiff State, shall provide written notice to defendants and the Divestiture Trustee, if there is one, stating whether or not it objects to the proposed divestiture. If plaintiff United States provides written notice that it does not object, the divestiture may be consummated, subject only to defendants' limited right to object to the sale under Section V.F of this Final Judgment. Absent written notice that plaintiff United States does not object to the proposed Acquirer or upon objection by plaintiff United States, a divestiture proposed under Section IV or Section V shall not be consummated. Upon objection by defendants under Section V.F, a divestiture proposed under Section V shall not be consummated unless approved by the Court.

VII. Financing

Defendants shall not finance all or any part of any divestiture made pursuant to Section IV or V of this Final Judgment.

VIII. Preservation of Assets

Until the divestitures required by this Final Judgment have been accomplished, defendants shall take all steps necessary to comply with the Preservation of Assets Stipulation and Order entered by this Court and cease use of the Divestiture Assets during the period that the Divestiture Assets arc managed by the Management Trustee. Defendants shall take no action that would jeopardize the divestitures ordered by this Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestitures have been completed under Section IV or V, defendants shall deliver to plaintiffs an affidavit as to the fact and manner of its compliance with Section IV or V of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts defendants have taken to solicit buyers for the Divestiture Assets, and to provide required information to prospective Acquirers, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by plaintiff United States upon consultation with the relevant plaintiff State, to information provided by defendants, including limitation on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, defendants shall deliver to plaintiffs an affidavit that describes in reasonable detail all actions defendants have taken and all steps defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. Defendants shall deliver to plaintiffs an affidavit describing any changes to the efforts and actions outlined in defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Defendants shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestitures have been completed.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, authorized representatives of the United States Department of Justice (including consultants and other persons retained by plaintiff United States) shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendants, be permitted:

(1) access during defendants' office hours to inspect and copy, or at plaintiff United States's option, to require defendants to provide hard copy or electronic copies of, all books, ledgers, accounts, records, data and documents in the possession, custody, or control of defendants, relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, defendants shall submit written reports or response to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by plaintiff United States to any person other than an authorized representative of the executive branch of plaintiff United States, any relevant plaintiff state, or, pursuant to a customary protective order or waiver of confidentiality by defendants, the FCC, except in the course of legal proceedings to which plaintiff United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by defendants to plaintiff United States, defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure, and defendants mark each

pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure,'' then plaintiff United States shall give defendants ten (10) calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XI. No Reacquisition

Defendants may not reacquire or lease any part of the Divestiture Assets during the term of this Final Judgment.

XII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

XIV. Public Interest Determination

Entry of this Final Judgment is in the public interest The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and plaintiff United States's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date:

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C 16

United States District Judge

In the United States District Court for the District of Columbia

United States of America, State of Alabama, State of California, State of Iowa, State of Kansas, State of Minnesota, State of North Dakota, and State of South Dakota, Plaintiffs, v. Verizon Communications Inc. and Alltel Corporation, Defendants

Case: 1:08–cv–01878. Assigned To: Sullivan, Emmet G. Assign Date: 10/30/2008. Description: Antitrust.

Competitive Impact Statement

Plaintiff United States of America (''United States''), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Turmey Act''), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

Defendants entered into an Agreement and Plan of Merger dated June 5, 2008, pursuant to which Verizon Communications Inc. (''Verizon'') will acquire Alltel Corporation (''Alltel''). Plaintiffs United States and the States of Alabama, California, Iowa, Kansas, Minnesota, North Dakota, and South Dakota filed a civil antitrust Complaint on October 30, 2008, seeking to enjoin the proposed acquisition. The Complaint alleges that the likely effect of this acquisition would be to lessen competition substantially for mobile wireless telecommunications services in 94 Cellular Market Areas (''CMAs'') in Alabama, Arizona, California, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, South Carolina, South Dakota, Utah, Virginia, and Wyoming where Verizon and Alltel are among the most significant competitors, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.[1] This loss of competition would result in consumers facing higher prices, lower quality service and fewer choices of mobile wireless telecommunications services providers.

At the same time the Complaint was filed, plaintiffs also filed a Preservation of Assets Stipulation and Order (''Stipulation'') and proposed Final Judgment, which are designed to eliminate the anticompetitive effects of the acquisition. Under the proposed Final Judgment, which is explained more fully below, defendants are required to divest mobile wireless telecommunications services businesses and related assets in the 94 CMAs (the ''Divestiture Assets''). Under the terms of the Stipulation, defendants will take certain steps to ensure that, during the pendency of the ordered divestitures, the Divestiture Assets are preserved and operated as competitively independent, economically viable ongoing businesses without influence by defendants.

Plaintiffs and defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof. Defendants have also stipulated that they will comply with the terms of the Stipulation and the proposed Final Judgment from the date of signing of the Stipulation, pending entry of the proposed Final Judgment by the Court and the required divestitures. Should the Court decline to enter the proposed Final Judgment, defendants have also committed to continue to abide by its requirements and those of Stipulation until the expiration of time for appeal.

II. Description of the Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Transaction

Verizon, with headquarters in New York, is a corporation organized and existing under the laws of the state of Delaware. Verizon is one of the world's largest providers of communications services. It is the second largest mobile wireless telecommunications services provider in the United States measured by subscribers, providing mobile wireless telecommunications services in 49 states to more than 70 million subscribers. In 2007, Verizon earned mobile wireless telecommunications services revenues of approximately $43 billion.

Alltel, a subsidiary of Atlantis Holdings LLC, is a corporation organized and existing under the laws of the State of Delaware, with headquarters in Little Rock, Arkansas. Alltel is the fifth largest mobile wireless telecommunications services provider in the United States measured by subscribers providing mobile wireless telecommunications services in 13 states to approximately 13 million subscribers. In 2007, Alltel earned approximately $8.8 billion in mobile wireless telecommunications services revenues.

Pursuant to an Agreement and Plan of Merger dated June 5, 2008, Verizon will acquire Alltel for approximately $28 billion. If this transaction is consummated, Verizon and Alltel combined would have approximately 83 million subscribers in the United States, with over $51 billion in mobile wireless telecommunications services revenues.

[1] In order to alleviate competitive concerns associated with the proposed acquisition, defendants also have agreed to divest wireless businesses in six additional CMAs, covered by the final judgments in *United States et al.* v. *Alltel Corp. et al.*, Civ. No. 06–3631 (RHKIAJB) (D. MN filed Sept. 7, 2006), and *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. 1:99CV01119 (EGS) (D.D.C. filed May 7, 1999), which prohibit defendants from reacquiring the wireless businesses in those CMAs. The wireless businesses in those CMAs will be divested pursuant to proposed modifications of those Final Judgments.

The proposed transaction, as initially agreed to by defendants, would lessen competition substantially for mobile wireless telecommunications services in a large number of CMAs in Alabama, Arizona, California, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, South Carolina, South Dakota, Utah, Virginia, and Wyoming. This acquisition is the subject of the Complaint and proposed Final Judgment filed by plaintiffs.

B. Mobile Wireless Telecommunications Services Industry

Mobile wireless telecommunications services allow customers to make and receive telephone calls and obtain data services using radio transmissions without being confined to a small area during the call or data session, and without the need for unobstructed line-of-sight to the radio tower. Mobility is highly valued by customers, as demonstrated by the more than 262 million people in the United States who own mobile wireless telephones. In 2007, revenues from the sale of mobile wireless telecommunications services in the United States were over $138 billion. To meet this desire for mobility, mobile wireless telecommunications services providers must deploy extensive networks of switches, radio transmitters, and receivers and interconnect their networks with the networks of wireline carriers and other mobile wireless telecommunications services providers.

In the early to mid-1980s, the FCC issued two cellular licenses (A-block and B-block) in each Metropolitan Statistical Area (''MSA'') and Rural Service Area (''RSA'') (collectively, CMAs), for a total of 734 CMAs covering the entire United States. Each license consists of 25 MHz of spectrum in the 800 MHz band. The first mobile wireless voice systems using this cellular spectrum were based on analog technology, now referred to as first-generation or ''1G'' technology.

In 1995, the FCC licensed additional spectrum for the provision of Personal Communications Services (''PCS''), a category of services that includes mobile wireless telecommunications services comparable to those offered by cellular licensees. These licenses are in the 1900 MHz band and are divided into six blocks: A, B, and C, which consist of 30 MHz each; and D, E, and F, which consist of 10 MHz each. Geographically, the A- and B-block 30 MHz licenses are issued by Major Trading Areas (''MTAs''). C-, D-, E-, and F-block licenses are issued by Basic Trading Areas (''BTAs''), several of which comprise each MTA. MTAs and BTAs do not generally correspond to MSAs and RSAs. With the introduction of the PCS licenses, both cellular and PCS licensees began offering digital services, thereby increasing network capacity, shrinking the size of handsets, and extending handset battery life. In addition, in 1996, a specialized mobile radio (''SMR'' or ''dispatch'') spectrum licensee, began using SMR spectrum to offer mobile wireless telecommunications services comparable to those offered by other mobile wireless telecommunications services providers, in conjunction with its dispatch, or ''push-to-talk,'' service.

Although there are a number of providers holding spectrum licenses in each area of the country, not all providers have fully built out their networks throughout each license area. In particular, because of the characteristics of PCS spectrum, providers holding this type of spectrum generally have found it less attractive to build out in rural areas.

Today, more than 95 percent of the total U.S. population lives in counties where three or more mobile wireless telecommunications services operators offer service. Nearly all mobile wireless voice services have migrated to the second-generation, or ''2G'' digital technologies, using GSM (global standard for mobility) or CDMA (code division multiple access). Even more advanced technologies (''2.5G'' and ''3G''), based on the earlier 2G technologies, have now been deployed for mobile wireless data services. Additionally, during the past two years, the FCC has auctioned off additional spectrum that can be used to support mobile wireless telecommunications services, including Advanced Wireless Spectrum (1710–1755 MHz and 2110–2155 MHz bands) and 700 MHz band spectrum, although it will be several years before mobile wireless telecommunications services utilizing this spectrum are widely deployed.

C. The Competitive Effects of the Transaction on Mobile Wireless Telecommunications Services

Mobile wireless telecommunications services include both voice and data services provided over a radio network and allow customers to maintain their telephone calls or data sessions without wires when traveling. There are no cost-effective alternatives to mobile wireless telecommunications services. Because fixed wireless services are not mobile, they are not regarded by consumers of mobile wireless telecommunications services to be a reasonable substitute for those services. It is unlikely that a sufficient number of customers would switch away from mobile wireless telecommunications services to make a small but significant price increase in those services unprofitable.

The United States comprises numerous local geographic markets for mobile wireless telecommunications services.[2] A large majority of customers use mobile wireless telecommunications services in close proximity to their workplaces and homes. Thus, customers purchasing mobile wireless telecommunications services choose among mobile wireless telecommunications services providers that offer services where they live, work, and travel on a regular basis. The geographic areas in which the FCC has licensed mobile wireless telecommunications services providers often represent the core of the business and social sphere within which customers have the same competitive choices for mobile wireless telephone services. The number and identity of mobile wireless telecommunications services providers varies among geographic areas, as does the quality of services and breadth of geographic coverage offered by providers. Some mobile wireless telecommunications services providers can and do offer different promotions, discounts, calling plans, and equipment subsidies in different geographic areas, varying the price for customers by geographic area.

The relevant geographic markets, under Section 7 of the Clayton Act, 15 U.S.C. § 18, where the transaction would substantially lessen competition for mobile wireless telecommunications services are effectively represented by the following FCC spectrum licensing areas:

(1) Lima OH MSA (CMA 158);
(2) Hickory NC MSA (CMA 166);
(3) Fargo-Moorhead ND-MN MSA (CMA 523);
(4) Mansfield OH MSA (CMA 231);
(5) Dothan AL MSA (CMA 246);
(6) Sioux City IA-NE MSA (CMA 253);
(7) Albany GA MSA (CMA 261);
(8) Danville VA MSA (CMA 262);
(9) Sioux Falls SD MSA (CMA 267);
(10) Billings MT MSA (CMA 268);
(11) Grand Forks ND-MN MSA (CMA 276);
(12) Rapid City SD MSA (CMA 289);
(13) Great Falls MT MSA (CMA 297);
(14) Bismarck ND MSA (CMA 298);
(15) Casper WY MSA (CMA 299);
(16) AL RSA 7 (CMA313);

[2] The existence of local markets does not preclude the possibility of competitive effects in a broader geographic area, such as a regional or national area, though plaintiff United States does not allege such effects in this transaction.

(17) AZ RSA 5 (CMA 322);
(18) CA RSA 6 (CMA 341);
(19) CO RSA 4 (CMA 351);
(20) CO RSA 5 (CMA 352);
(21) CO RSA 6 (CMA 353);
(22) CO RSA 7 (CMA 354);
(23) CO RSA 8 (CMA 355);
(24) CO RSA 9 (CMA 356);
(25) GA RSA 6 (CMA 376);
(26) GA RSA 7 (CMA 377);
(27) GA RSA 8 (CMA 378);
(28) GA RSA 9 (CMA 379);
(29) GA RSA 10 (CMA 380);
(30) GA RSA 12 (CMA 382);
(31) GA RSA 13 (CMA 383);
(32) ID RSA 2 (CMA 389);
(33) ID RSA 3 (CMA 390);
(34) IL RSA 8 (CMA 401);
(35) IL RSA 9 (CMA 402);
(36) IA RSA 8 (CMA 419);
(37) KS RSA 1 (CMA 428);
(38) KS RSA 2 (CMA 429);
(39) KS RSA 6 (CMA 433);
(40) KS RSA 7 (CMA 434);
(41) KS RSA 11 (CMA438);
(42) KS RSA 12 (CMA 439);
(43) KS RSA 13 (CMA 440);
(44) MN RSA 1 (CMA 482);
(45) MN RSA 2 (CMA 483);
(46) MN RSA 7 (CMA 488);
(47) MT RSA 1 (CMA 523);
(48) MT RSA 2 (CMA 524);
(49) MT RSA 4 (CMA 526);
(50) MT RSA 5 (CMA 527);
(51) MT RSA 6 (CMA 528);
(52) MT RSA 7 (CMA 529);
(53) MT RSA 8 (CMA 530);
(54) MT RSA 9 (CMA 531);
(55) MT RSA 10 (CMA 532);
(56) NE RSA 5 (CMA 537);
(57) NV RSA 2 (CMA 544);
(58) NV RSA 5 (CMA 547);
(59) NM RSA 1 (CMA 553);
(60) NM RSA 5 (CMA 557);
(61) NM RSA 6 (CMA 558);
(62) NC RSA 2 (CMA 566);
(63) NC RSA 5 (CMA 569);
(64) ND RSA 1 (CMA 580);
(65) ND RSA 2 (CMA 581);
(66) ND RSA 3 (CMA 582);
(67) ND RSA 4 (CMA 583);
(68) ND RSA 5 (CMA 584);
(69) OH RSA 2 (CMA 586);
(70) OH RSA 5 (CMA 589);
(71) OH RSA 6 (CMA 590);
(72) SC RSA 1 (CMA 625);
(73) SC RSA 2 (CMA 626);
(74) SC RSA 3 (CMA 627);
(75) SC RSA 7 (CMA 631);
(76) SD RSA 1 (CMA 634);
(77) SD RSA 2 (CMA 635);
(78) SD RSA 3 (CMA 636);
(79) SD RSA 4 (CMA 637);
(80) SD RSA 5 (CMA 638);
(81) SD RSA 6 (CMA 639);
(82) SD RSA 7 (CMA 640);
(83) SD RSA 8 (CMA 641);
(84) SD RSA 9 (CMA 642);
(85) UT RSA 3 (CMA 675);
(86) UT RSA 4 (CMA 676);
(87) UT RSA 5 (CMA 677);
(88) UT RSA 6 (CMA 678);
(89) VA RSA 1 (CMA 681);
(90) VA RSA 8 (CMA 688);
(91) WY RSA 1 (CMA 718);
(92) WY RSA 2 (CMA 719);
(93) WY RSA 4 (CMA 721); and
(94) WY RSA 5 (CMA 722).

It is unlikely that a sufficient number of customers would switch to mobile wireless telecommunications services providers who do not offer services in these geographic areas to make a small but significant price increase in the relevant geographic markets unprofitable.

These geographic areas of concern for mobile wireless telecommunications services were identified via a fact-specific, market-by-market analysis that included consideration of, but was not limited to, the following factors: the number of mobile wireless telecommunications services providers and their competitive strengths and weaknesses; Verizon's and Alltel's market shares, along with those of the other providers; whether additional spectrum is, or is likely soon to be, available; whether any providers are limited by insufficient spectrum or other factors in their ability to add new customers; concentration in the market, and the breadth and depth of coverage by different providers in each area and in the surrounding area; each carrier's network coverage in relationship to the population density of the license area; each provider's retail presence; local wireless number portability data; and the likelihood that any provider would expand its existing coverage or that new providers would enter.

Verizon and Alltel are significant providers of mobile wireless telecommunications services in each of the CMAs listed above. Their combined share of subscribers in each area ranges from over 55 percent to 100 percent. In addition, each is the other's closest competitor for a significant set of customers.

Verizon and Alltel each hold cellular spectrum licenses in all but two of these CMAs Verizon does not own cellular spectrum in the other two CMAs—NE RSA 5 and MN RSA 7—but is a strong competitor because, unlike many other providers with PCS spectrum in rural areas, it has constructed a PCS network that covers a significant portion of the population. Considering these factors, defendants Verizon and Alltel are also strong and close competitors considering their brand recognition, service quality and reputation, coverage, handset selection, and service features.

The relevant geographic markets for mobile wireless services are highly concentrated. As measured by the Herfindahl-Hirschman Index (''HHI''), which is commonly employed in merger analysis and is defined and explained in Appendix B to the Complaint, concentration in these geographic areas ranges from over 2100 to more than 9100, which is well above the 1800 threshold at which plaintiffs consider a market to be highly concentrated. After Verizon's proposed acquisition of Alltel is consummated, the HHIs in the relevant geographic areas will range from over 4000 to 10,000, with increases in the HHI as a result of the merger ranging from over 300 to over 4900, significantly beyond the thresholds at which plaintiffs consider a transaction likely to cause competitive harm.

Competition between Verizon and Alltel in the relevant geographic areas has resulted in lower prices and higher quality in mobile wireless telecommunications services than otherwise would have existed in these geographic areas. If Verizon's proposed acquisition of Alltel is consummated, competition between Verizon and Alltel in mobile wireless telecommunications services will be eliminated in these areas. As a result, the loss of competition between Verizon and Alltel increases the merged firm's incentive and ability in the relevant geographic markets to increase prices, diminish the quality or quantity of services provided, and refrain from or delay making investments in network improvements.

Entry by a new mobile wireless services provider in the relevant geographic areas would be difficult, time-consuming, and expensive, requiring spectrum licenses and the build out of a network. Therefore, any entry in response to a small but significant price increase for mobile wireless telecommunications services by the merged firm in these relevant geographic areas would not be timely, likely, or sufficient to thwart the competitive harm resulting from Verizon's proposed acquisition of Alltel, if it were consummated without the divestitures provided for in the proposed Final Judgment.

For these reasons, plaintiffs concluded that Verizon's proposed acquisition of Alltel likely would substantially lessen competition, in violation of Section 7 of the Clayton Act, in the provision of mobile wireless telecommunications services in the relevant geographic areas alleged in the Complaint.

III. Explanation of the Proposed Final Judgment

The divestiture requirements of the proposed Final Judgment will eliminate the anticompetitive effects of the acquisition in mobile wireless telecommunications services in the geographic areas of concern. The proposed Final Judgment requires defendants to divest the Divestiture Assets within one hundred twenty days after the consummation of the Transaction, or five days after notice of the entry of the Final Judgment by the Court, whichever is later. The Divestiture Assets are essentially the entire mobile wireless telecommunications services businesses of one of the merging companies in the geographic areas described herein where Verizon and Alltel are each other's close competitors for mobile wireless telecommunications services. These assets must be divested in such a way as to satisfy plaintiff United States in its sole discretion upon consultation with the relevant plaintiff state that the assets will be operated by the purchaser as a viable, ongoing business that can compete effectively in each relevant area. Defendants must take all reasonable steps necessary to accomplish the divestitures quickly and shall cooperate with prospective purchasers.

The proposed Final Judgment requires that a single purchaser acquire all of the Divestiture Assets in each of the following numbered subsections:

(1) Alabama (a) Dothan MSA (CMA 246); (b) ALRSA7 (CMA313);

(2) Colorado (a) CO RSA 4 (CMA 351); (b) CO RSA 5 (CMA 352); (c) CO RSA 6 (CMA 353); (d) CO RSA 7 (CMA 354); (e) CO RSA 8 (CMA 355); (f) CO RSA 9 (CMA 356);

(3) Georgia (a) Albany MSA (CMA 261); (b) GA RSA 6 (CMA 376); (c) GA RSA 7 (CMA 377); (d) GA RSA 8 (CMA 378); (e) GA RSA 9 (CMA 379); (f) GA RSA 10 (CMA 380); (g) GA RSA 12 (CMA 382); (h) GA RSA 13 (CMA 383);

(4) Idaho (a) ID RSA 2 (CMA 389); (b) ID RSA 3 (CMA 390);

(5) Illinois (a) IL RSA 8 (CMA 401); (b) IL RSA 9 (CMA 402);

(6) Iowa/Nebraska (a) Sioux City MSA (CMA 253); (b) IA RSA 8 (CMA 419); (c) NE RSA 5 (CMA 537);

(7) Kansas (a) KS RSA 1 (CMA 428); (b) KS RSA 2 (CMA 429); (c) KS RSA 6 (CMA 433); (d) KS RSA 7 (CMA 434); (e) KS RSA 11 (CMA 438); (f) KS RSA 12 (CMA 439); (g) KS RSA 13 (CMA 440);

(8) Southern Minnesota[3] (a) MN RSA 7 (CMA 488);

(9) Montana (a) Billings (CMA 268); (b) Great Falls (CMA 297); (c) MT RSA 1 (CMA 523); (d) MT RSA 2 (CMA 524); (e) MT RSA 4 (CMA 526); (f) MT RSA 5 (CMA 527); (g) MT RSA 6 (CMA 528); (h) MT RSA 7 (CMA 529); (i) MT RSA 8 (CMA 530); (j) MT RSA 9 (CMA 531); (k) MT RSA 10 (CMA 532);

(10) Nevada (a) NV RSA 2 (CMA 544); (b) NV RSA 5 (CMA 547);

(11) New Mexico[4] (a) NM RSA 5 (CMA 557); (b) NM RSA 6 (CMA 558);

(12) North Carolina (a) Hickory MSA (CMA 166); (b) NC RSA 2 (CMA 566); (c) NC RSA 5 (CMA 569);

(13) North Dakota/Northern Minnesota (a) Fargo-Moorhead ND-MN (CMA 523); (b) Grand Forks ND-MN (CMA 276); (c) Bismarck MSA (CMA 298); (d) MN RSA 1 (CMA 482); (e) MN RSA 2 (CMA 483); (f) ND RSA 1 (CMA 580); (g) ND RSA2 (CMA 581); (h) ND RSA 3 (CMA 582); (i) NI RSA 4 (CMA 583); (j) ND RSA 5 (CMA 584);

(14) Ohio[5] (a) Lima MSA (CMA 158); (b) Mansfield MSA (CMA 231); (c) OH RSA 2 (CMA 586); (d) OH RSA 5 (CMA 589); (e) OH RSA 6 (CMA 590);

(15) South Carolina[6] (a) SC RSA 1 (CMA 625); (b) SC RSA 2 (CMA 626); (c) SC RSA 3 (CMA 627); (d) SC RSA 7 (CMA 631);

(16) South Dakota (a) Sioux Falls MSA (CMA 267); (b) Rapid City MSA (CMA 289); (c) SD RSA 1 (CMA 634); (d) SD RSA 2 (CMA 635); (e) SD RSA 3 (CMA 636); (f) SD RSA 4 (CMA 637); (g) SD RSA 5 (CMA 638); (h) SD RSA 6 (CMA 639); (i) SD RSA 7 (CMA 640); (j) SD RSA 8 (CMA 641); (k) SD RSA 9 (CMA 642);

(17) Utah (a) UT RSA 3 (CMA 675); (b) UT RSA 4 (CMA 676); (c) UT RSA 5 (CMA 677); (d) UT RSA 6 (CMA 678);

(18) Wyoming (a) Casper MSA (CMA 299); (b) WY RSA 1 (CMA 718); (c) WY RSA 2 (CMA 719); (d) WY RSA 4 (CMA 721); (e) WY RSA 5 (CMA 722).

The CMAs have been grouped to reflect the fact that carriers frequently are more competitive where they serve contiguous areas. Some customers often travel across FCC licensing areas, so operating a larger contiguous service area can be an important feature for selling the product in each affected market. Moreover, there may be significant efficiencies associated with serving a broader geographic area. In deciding on the particular packages to require, plaintiff United States recognized that selling areas with significant linkages across these areas provides greater assurance that the buyer will be an effective competitor. Plaintiff United States also recognized, however, that larger packages might discourage potential buyers who might otherwise have the strongest incentives to replace the lost competition in any one particular area. The proposed Final Judgment strikes a balance between these potential issues by creating bundles that are geographically linked but allowing potential buyers to effectively suggest larger packages by bidding conditionally on multiple packages. The proposed Final Judgment also gives plaintiff United States in its sole discretion upon consultation with the relevant plaintiff State the flexibility to allow even smaller packages of assets as appropriate to ensure a successful divestiture.

A. Timing of Divestitures

In antitrust cases involving mergers or joint ventures in which the United States seeks a divestiture remedy, it requires completion of the divestitures within the shortest time period reasonable under the circumstances. Section IV.A of the proposed Final Judgment in this case requires divestiture of the Divestiture Assets, within 120 days after the consummation of the Transaction, or five days after notice of the entry of the Final Judgment by the Court, whichever is later. Plaintiff United States in its sole discretion, upon consultation with the relevant plaintiff State, may extend the date for divestiture of the Divestiture

[3] In addition, defendants will divest the wireless businesses in MN RSAs 7 through 10, recently acquired by Verizon from Rural Cellular Corporation, pursuant to the proposed Modified Final Judgment in *United States et al.* v. *Alltel Corp. et al.*, Civ. No. 06–3631 (RHKJAJB) (D. MN filed Sept. 7, 2006), to the same acquirer as the acquirer of the Divestiture Assets in the CMA specified in this subsection.

[4] In addition, defendants will divest the wireless business in the Las Cruces MSA (CMA 285), currently owned by Alltel, pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. 1 :99CV01 119 (EGS) (D.D.C. filed May 7, 1999), to the same acquirer as the acquirer of the Divestiture Assets in the CMAs specified in this subsection.

[5] In addition, defendants will divest the wireless business in OH RSA 3 (CMA 587), currently owned by Alltel, pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. I :99CV01 19 (EGS) (DD.C. filed May 7, 1999), to the same acquirer as the acquirer of the Divestiture Assets in the CMAs specified in this subsection.

[6] In addition, defendants will divest the wireless business in the Anderson MSA (CMA 227), currently owned by Alltel, pursuant to the proposed Modified Final Judgment in *United States* v. *Bell Atlantic Corp. et al.*, Civ. No. 1 :99C VOl 19 (EGS) (D.D.C. May 7, 1999), to the same acquirer as the acquirer of the Divestiture Assets in the CMA specified in this subsection.

Assets by up to 60 days. Because the FCC's approval is required for the transfer of the wireless licenses to a purchaser, Section IV.A provides that if applications for transfer of a wireless license have been filed with the FCC, but the FCC has not acted dispositively before the end of the required divestiture period, the period for divestiture of those assets shall be extended until five days after the FCC has acted. This extension is to be applied only to the individual Divestiture Assets affected by the delay in approval of the license transfer and does not entitle defendants to delay the divestiture of any other Divestiture Assets for which license transfer approval is not required or has been granted.

The divestiture timing provisions of the proposed Final Judgment will ensure that the divestitures are carried out in a timely manner, and at the same time will permit defendants an adequate opportunity to accomplish the divestitures through a fair and orderly process. Even if all Divestiture Assets have not been divested upon consummation of the transaction, there should be no adverse impact on competition given the limited duration of the period of common ownership and the detailed requirements of the Stipulation.

B. Use of a Management Trustee

The Stipulation filed simultaneously with this Competitive Impact Statement ensures that the Divestiture Assets remain an ongoing business concern prior to divestiture. To accomplish this objective, the Stipulation provides for the appointment of a management trustee selected by plaintiff United States upon consultation with the plaintiff States, to oversee the operations of the Divestiture Assets. The appointment of a management trustee is appropriate because the Divestiture Assets are not independent facilities that can be held separate and operated as stand alone units, but are an integral part of a larger network which, to maintain their competitive viability and economic value, should remain part of that network during the divestiture period. A management trustee will oversee the continuing relationship between defendants and these assets to ensure that these assets are preserved and supported by defendants during this period, yet run independently. The management trustee will have the power to operate the Divestiture Assets in the ordinary course of business, so that they will remain independent and uninfluenced by defendants and so that the Divestiture Assets are preserved and operated as an ongoing and economically viable competitor to defendants and to other mobile wireless telecommunications services providers. The management trustee will preserve the confidentiality of competitively sensitive marketing, pricing, and sales information; ensure defendants' compliance with the Stipulation and the proposed Final Judgment; and maximize the value of the Divestiture Assets so as to permit expeditious divestiture in a manner consistent with the proposed Final Judgment.

The Stipulation provides that defendants will pay all costs and expenses of the management trustee, including the cost of consultants, accountants, attorneys, and other representatives and assistants hired by the management trustee as are reasonably necessary to carry out his or her duties and responsibilities. After his or her appointment becomes effective, the management trustee will file monthly reports with plaintiffs setting forth efforts taken to accomplish the goals of the Stipulation and the proposed Final Judgment and the extent to which defendants are fulfilling their responsibilities. Finally, the management trustee may become the divestiture trustee, pursuant to the provisions of Section V of the proposed Final Judgment.

C. Use of a Divestiture Trustee

In the event that defendants do not accomplish the divestiture within the periods prescribed in the proposed Final Judgment, the Final Judgment provides that the Court will appoint a trustee selected by plaintiff United States upon consultation with the relevant plaintiff State, to effect the divestitures. As part of this divestiture, defendants must continue, as has been the practice while the businesses have been managed by the Management Trustee, to relinquish any direct or indirect financial control and any direct or indirect role in management. Pursuant to Section V of the proposed Final Judgment, the divestiture trustee will have the legal right to control the Divestiture Assets until they are sold to a final purchaser, subject to safeguards to prevent defendants from influencing their operation.

Section V details the requirements for the establishment of the divestiture trust, the selection and compensation of the divestiture trustee, the responsibilities of the divestiture trustee in connection with the divestiture and operation of the Divestiture Assets, and the termination of the divestiture trust. The divestiture trustee will have the obligation and the sole responsibility, under Section V.D, for the divestiture of any transferred Divestiture Assets. The divestiture trustee has the authority to accomplish divestitures at the earliest possible time and ''at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee.'' In addition, to ensure that the divestiture trustee can promptly locate and divest to an acceptable purchaser, plaintiff United States, in its sole discretion upon consultation with the relevant plaintiff State, may require defendants to include additional assets, or allow defendants to substitute substantially similar assets, which substantially relate to the Divestiture Assets to be divested by the divestiture trustee.

The divestiture trustee will not only have responsibility for sale of the Divestiture Assets, but will also be the authorized holder of the wireless licenses, with full responsibility for the operations, marketing, and sales of the wireless businesses to be divested, and will not be subject to any control or direction by defendants. Defendants will continue to have no role in the operation, or management of the Divestiture Assets other than the right to receive the proceeds of the sale. Defendants will also retain certain obligations to support the Divestiture Assets and cooperate with the divestiture trustee in order to complete the divestiture.

The proposed Final Judgment provides that defendants will pay all costs and expenses of the divestiture trustee. The divestiture trustee's commission will be structured, under Section V.G of the proposed Final Judgment, so as to provide an incentive for the divestiture trustee based on the price obtained and the speed with which the divestitures are accomplished. After his or her appointment becomes effective, the divestiture trustee will file monthly reports with the Court and plaintiffs setting forth his or her efforts to accomplish the divestitures. Section V.J requires the divestiture trustee to divest the Divestiture Assets to an acceptable purchaser or purchasers no later than six months after the assets are transferred to the divestiture trustee. At the end of six months, if all divestitures have not been accomplished, the trustee and plaintiffs will make recommendations to the Court, which shall enter such orders as appropriate in order to carry out the purpose of the Final Judgment, including extending the trust or term of the trustee's appointment

The divestiture provisions of the proposed Final Judgment will eliminate

the anticompetitive effects of the transaction in the provision of mobile wireless telecommunications services. The divestitures of the Divestiture Assets will preserve competition in mobile wireless telecommunications services by maintaining an independent and economically viable competitor in the relevant geographic areas.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, IS U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against defendants.

V. Procedures Available for Modification of the Proposed Judgment

The United States and defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty days of the date of publication of this Competitive Impact Statement in the **Federal Register** or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, which ever is later. All comments received during this period will be considered by the Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of plaintiff United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to:

Nancy M. Goodman, Chief, Telecommunications and Media Enforcement Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 8000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgement

Plaintiffs considered, as an alternative to the proposed Final Judgment, a full trial on the merits against defendants. Plaintiffs could have continued the litigation and sought preliminary and permanent injunctions against Verizon's acquisition of Alltel. Plaintiffs are satisfied, however, that the divestiture of assets and other relief described in the proposed Final Judgment will preserve competition for the provision of mobile wireless telecommunications services in the relevant areas identified in the Complaint.

VII. Standard of Review Under the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(l). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> A. The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> B. The impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. l6(e)(l)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reach of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cii. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1, 11 (D.D.C. 2007) (assessing the public interest standard under the Tunney Act).[7]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. See Microsoft, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' United States v. BNS. Inc., 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); see also *Microsoft,* 56 F.3d at 1460–62; United States v. Alcoa, Inc., 152 F. Supp. 2d 37, 40 (D.D.C. 2001). Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[8] In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC*

[7] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. 16(e) (2004), *with* 15 U.S.C. I 6(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

[8] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the {APPAJ is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies {obtained in the decree are} so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

Commc'ns, 489 F. Supp. 2d at 17; *see also Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have great flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel, & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); see also *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. Id. at 145 9–60. As this Court recently confirmed in SBC Communications, courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction ''[nothing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). The language wrote into the statute what the Congress that enacted the Tunney Act in 1974 intended, as Senator Tunney then explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[9]

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by plaintiff United States in formulating the proposed Final Judgment.

Dated: October 30, 2008

Respectfully submitted,

Hillary B. Burchuk (D.C. Bar No. 366755)

Lawrence M. Frankel (D.C. Bar No. 441532)

Jared A. Hughes

Attorneys, Telecommunications & Media, Enforcement Section, Antitrust Division, U.S. Department of Justice, City Center Building, 1401 H Street, N.W., Suite 8000, Washington, D.C. 20530, (202) 514–5621, *Facsimile:* (202) 514–6381.

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[9] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am Dairymen, Inc.,* 1977–1 Trade Cas. (CCII) ¶ 61,508, at 71,980 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Bell Atlantic Corporation; Proposed Modification of Final Judgment

Notice is hereby given that a Motion to Modify the Final Judgment, Stipulation, and Memorandum in Support of the Motion to Modify the Final Judgment, have been filed with the United States District Court for the District of Columbia in *United States* v. *Bell Atlantic Corporation,* Civil No. 1 :99CV0 1119. On May 7, 1999, the United States filed a Complaint (and a Supplemental Complaint on December 6, 1999) alleging that the proposed merger between Bell Atlantic Corporation and GTE Corporation (the merged firm known as ''Verizon Communications Inc.'') and the proposed joint venture between Bell Atlantic and Vodafone AirTouch Plc (the joint venture now known as ''Verizon Wireless'') would violate Section 7 of the Clayton Act, 15 U.S.C. 18, by substantially lessening competition in wireless mobile telephone service in certain areas of Alabama, Arizona, California, Florida, Idaho, Illinois, Indiana, Montana, New Mexico, Ohio, South Carolina, Texas, Virginia, Washington, and Wisconsin.

The Final Judgment, entered on April 18, 2000, required the defendants to divest certain mobile wireless telecommunications services businesses. Divestitures were made to Ailtel in 25 Cellular Market Areas (''CMAs''). The modification would allow the defendants to reacquire the divested wireless system assets in 22 of those CMAs—Cleveland MSA (CMA 16), Tampa MSA (CMA 22), Phoenix MSA (CMA 26), Akron MSA (CMA 52), Greenville SC MSA (CMA 67), Tucson MSA (CMA 77), El Paso TX MSA (CMA 81), Mobile MSA (CMA 83), Albuquerque MSA (CMA 86), Canton MSA (CMA 87), Lakeland MSA (CMA 114), Pensacola MSA (CMA 127), Lorain MSA (CMA 136), Ft. Myers MSA (CMA 164), Sarasota MSA (CMA 167), Bradenton MSA (CMA 211), AZ RSA 2 (CMA 319), FL RSA 1 (CMA 360), FL RSA 2 (CMA 361), FL RSA 3 (CMA 362), FL RSA 4 (CMA 363), and FL RSA 11 (CMA 370). The modification would allow the defendants to reacquire three additional CMAs—Anderson SC MSA (CMA 227), Las Cruces NM MSA (CMA 285) and OH RSA 3 (CMA 587)—only until the assets are divested according to terms specified in the Modified Final Judgment.

Copies of the Motion to Modify the Final Judgment, Stipulation, Memorandum in Support of the Motion to Modify the Final Judgment, and all other papers with the Court in connection with the motion are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 450 Fifth Street, NW., Suite 1010, Washington, DC 20530 (202–514–2481), on the Department of Justice Web site (*http://www.usdoj.gov/atr*), and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice Regulations. Public comment is invited within 30 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Nancy Goodman, Chief, Telecommunications & Media Enforcement Section, Antitrust Division, U.S. Department of Justice, City Center Building, 1401 H Street, NW., Suite 8000, Washington, DC 20530 (202–514–5621).

J. Robert Kramer II,

Director of Operations, Antitrust Division.

[FR Doc. E8–26563 Filed 11–10–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–307F]

Controlled Substances: Final Revised Aggregate Production Quotas for 2008

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of final aggregate production quotas for 2008.

SUMMARY: This notice establishes final 2008 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA). The DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2008 published July 1, 2008 (73 FR 37496).

DATES: *Effective Date:* November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant 28 CFR 0.104.

The 2008 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2008 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances.

On July 1, 2008, a notice of the proposed revised 2008 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (73 FR 37496). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before July 31, 2008.

Five companies commented on a total of 25 schedules I and II controlled substances within the published comment period. One additional comment was received after the comment period ended and therefore was not considered. Five companies proposed that the aggregate production quotas for amphetamine (for sale), codeine (for sale), codeine (for conversion), dextropropoxyphene, dihydromorphine, diphenoxylate, fentanyl, gamma-hydroxybutyric acid, hydrocodone (for sale), hydromorphone, methadone, methadone intermediate, morphine (for sale), morphine (for conversion), nabilone, noroxymorphone (for conversion), opium, oripavine, oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), oxymorphone (for conversion), sufentanil, tetrahydrocannabinols, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2007 year-end inventories, initial 2008 manufacturing quotas, 2008 export requirements, actual and projected 2008 sales, research, product development requirements and additional applications received. Based on this information, the DEA has adjusted the final 2008 aggregate production quotas for codeine (for conversion), diphenoxylate, heroin, hydrocodone (for sale), morphine (for conversion), nabilone, noroxymorphone (for conversion), oxymorphone (for conversion), phenazocine, and phenylacetone to meet the legitimate needs of the United States.

Regarding amphetamine (for sale), codeine (for sale), dextropropoxyphene, dihydromorphine, fentanyl, gamma-hydroxybutyric acid, hydromorphone, methadone, methadone intermediate, morphine (for sale), opium, oripavine, oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), sufentanil, tetrahydrocannabinols, and thebaine, the DEA has determined that the proposed revised 2008 aggregate production quotas are sufficient to meet the current 2008 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. 826), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator, pursuant to 28 CFR 0.104, the Deputy Administrator hereby orders that the 2008 final aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—Schedule I	Final revised 2008 quotas (grams)
2,5-Dimethoxyamphetamine	2
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)	10
3-Methylfentanyl	2
3-Methylthiofentanyl	2

Basic class—Schedule I	Final revised 2008 quotas (grams)
3,4-Methylenedioxyamphetamine (MDA)	20
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10
3,4-Methylenedioxymethamphetamine (MDMA)	22
3,4,5-Trimethoxyamphetamine	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	7
4-Methoxyamphetamine	77
4-Methylaminorex	2
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12
5-Methoxy-3,4-methylenedioxyamphetamine	2
5-Methoxy-N,N-diisopropyltryptamine	5
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
Alpha-ethyltryptamine	2
Alphameprodine	2
Alphamethadol	3
Alpha-methylfentanyl	2
Alpha-methylthiofentanyl	2
Alpha-methyltryptamine	5
Aminorex	8
Benzylmorphine	2
Betacetylmethadol	2
Beta-hydroxy-3-methylfentanyl	2
Beta-hydroxyfentanyl	2
Betameprodine	2
Betamethadol	2
Betaprodine	2
Bufotenine	8
Cathinone	3
Codeine-N-oxide	302
Diethyltryptamine	2
Difenoxin	50
Dihydromorphine	2,549,000
Dimethyltryptamine	3
Gamma-hydroxybutyric acid	21,940,000
Heroin	20
Hydromorphinol	3,000
Hydroxypethidine	2
Ibogaine	1
Lysergic acid diethylamide (LSD)	61
Marihuana	4,500,000
Mescaline	2
Methaqualone	10
Methcathinone	4
Methyldihydromorphine	2
Morphine-N-oxide	310
N,N-Dimethylamphetamine	7
N-Ethylamphetamine	2
N-Hydroxy-3,4-methylenedioxyamphetamine	2
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	16
Para-fluorofentanyl	2
Phenomorphan	2
Pholcodine	2
Psilocybin	7
Psilocyn	7
Tetrahydrocannabinols	312,500
Thiofentanyl	2
Trimeperidine	2

Basic class—Schedule II	Final revised 2008 quotas (grams)
1-Phenylcyclohexylamine	2
Alfentanil	8,000
Alphaprodine	2

Basic class—Schedule II	Final revised 2008 quotas (grams)
Amobarbital	3
Amphetamine (for sale)	17,000,000
Amphetamine (for conversion)	5,000,000
Cocaine	247,000
Codeine (for sale)	39,605,000
Codeine (for conversion)	71,000,000
Dextropropoxyphene	106,000,000
Dihydrocodeine	1,200,000
Diphenoxylate	761,000
Ecgonine	83,000
Ethylmorphine	2
Fentanyl	1,428,000
Glutethimide	2
Hydrocodone (for sale)	55,000,000
Hydrocodone (for conversion)	1,500,000
Hydromorphone	3,300,000
Isomethadone	2
Levo-alphacetylmethadol (LAAM)	3
Levomethorphan	5
Levorphanol	10,000
Lisdexamfetamine	6,200,000
Meperidine	8,600,000
Metazocine	1
Methadone (for sale)	25,000,000
Methadone Intermediate	26,000,000
Methamphetamine	3,130,000
[680,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,405,000 grams for methamphetamine mostly for conversion to a schedule III product; and 45,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000
Morphine (for sale)	35,000,000
Morphine (for conversion)	110,000,000
Nabilone	5,502
Noroxymorphone (for sale)	10,000
Noroxymorphone (for conversion)	9,000,000
Opium	1,400,000
Oripavine	15,000,000
Oxycodone (for sale)	70,000,000
Oxycodone (for conversion)	4,820,000
Oxymorphone (for sale)	2,000,000
Oxymorphone (for conversion)	12,000,000
Pentobarbital	28,000,000
Phenazocine	1
Phencyclidine	2,021
Phenmetrazine	2
Phenylacetone	1
Racemethorphan	2
Remifentanil	410
Secobarbital	2
Sufentanil	10,300
Thebaine	126,000,000

The Deputy Administrator further orders that the aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 shall be zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and

3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more in any one year, and 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.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 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.

Dated: October 31, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–26798 Filed 11–10–08; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–087)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Kaprice L. Harris, Attorney Advisor, Glenn Research Center at Lewis Field, Code 500–118, Cleveland, OH 44135; telephone (216) 433–5754; fax (216) 433–6790.

NASA Case No. LEW–18324–1: Semiconductor Metal Oxide Modified Solid Electrolyte Carbon Dioxide Microsensors with Reduced Operation Temperature;

NASA Case No. LEW–18048–1: Two and Three Dimensional Near Infrared Subcutaneous Structure Images Using Real Time Nonlinear Video Processing;

NASA Case No. LEW–18362–1: Space Radiation Detector with Spherical Geometry.

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26824 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–088)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Bryan A. Geurts, Patent Counsel, Goddard Space Flight Center, Mail Code 140.1, Greenbelt, MD 20771–0001; telephone (301) 286–7351; fax (301) 286–9502.

NASA Case No. GSC–15158–1: Nanophase Dispersion Strengthened Low CTE Alloy;

NASA Case No. GSC–15364–1: Particle Surface Interaction Model and Method of Determining Particle Surface Interactions;

NASA Case No. GSC–15217–1: Spaceflight High Data Rate Radiation Hard KA–Band Modulator;

NASA Case No. GSC–15163–1: Detector for Dual Band Ultraviolet Detection;

NASA Case No. GSC–15445–1: Improved Time Delay and Distance Measurement;

NASA Case No. GSC–15416–1: Directed Flux Motor utilizing Concentric Magnets and Interwoven Flux Channels;

NASA Case No. GSC–15417–1: Joint Assembly;

NASA Case No. GSC–15419–1: Walk and Roll Robot;

NASA Case No. GSC–15208–1: Direct Solve Image Based Wavefront Sensing;

NASA Case No. GSC–15349–1: Multiple Frequency Optical Mixer and Demultiplexer and Apparatus for Remote Sensing;

NASA Case No. GSC–15136–1: Blocking Contacts for N–Type Cadmium Zinc Telluride;

NASA Case No. GSC–15470–1: Broadband Planar Magic-T with Low-Phase and Amplitude Imbalance;

NASA Case No. GSC–15483–1: A Method and Apparatus for Relative Navigation Using Reflected GPS Signals.

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26818 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–089)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Mark W. Homer, Patent Counsel, NASA Management Office—JPL, 4800 Oak Grove Drive, Mail Stop 180–200, Pasadena, CA 91109; telephone (818) 354–7770.

NASA Case No. DRC–008–023: Improved Process for Using Surface Strain Measurements to Obtain Operational Loads for Complex Structures;

NASA Case No. NPO–45462–1: System and Method for Critical Coupling to an Optical Resonator;

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26820 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–091)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the

National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Linda B. Blackburn, Patent Counsel, Langley Research Center, Mail Code 141, Hampton, VA 23681–2199; telephone (757) 864–3221; fax (757) 864–9190.

NASA Case No. LAR–17548–1: Combination Structural Support and Thermal Protection System;

NASA Case No. LAR–17427–1: Tailorable Dielectric Material with Complex Permitivity Characteristics;

NASA Case No. LAR–17573–1: Air-Coupled Acoustic Thermography for In-Situ Evaluation;

NASA Case No. LAR–17391–1: Byzantine-Fault Tolerant Self-Stabilizing Protocol for Distributed Clock Synchronization Systems.

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26821 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–085)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: James J. McGroary, Patent Counsel, Marshall Space Flight Center, Mail Code LS01, Huntsville, AL 35812; telephone (256) 544–0013; fax (256) 544–0258.

NASA Case No. MFS–32318–1: Systems, Methods and Apparatus for Position Sensor Digital Conditioning Electronics;

NASA Case No. MFS–32005–1: Fluid Mixing Plug with Metering Capabilities;

NASA Case No. MFS–32341–1: Seal Apparatus and Methods to Manufacture Thereof;

NASA Case No. MFS–32605–1: Novel Grazing Incidence Neutron Optics;

NASA Case No. MFS–32228–1: Short-Range Communication System.

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26822 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–086)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: Patent applications on the inventions listed below assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Robert M. Padilla, Patent Counsel, Ames Research Center, Code 202A–4, Moffett Field, CA 94035–1000; telephone (650) 604–5104; fax (650) 604–2767.

NASA Case No. ARC–16018–1: Versatile Honeycomb Matrix Heat Shield;

NASA Case No. ARC 14950–2: Enhanced Project Management Tool.

Dated: November 4, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26823 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–092)]

Notice of Intent To Grant Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant an exclusive, worldwide license to practice the invention described in Invention Disclosure SSC–00247 entitled ''Wireless Strain Gage Technology used for Valve Health Monitoring'' to Aegis Stress Technology, Inc., having its principal place of business in Murrysville, PA. The patent rights in this invention are assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of the Chief Counsel, Mail Code CC–A, NASA John F. Kennedy Space Center, Kennedy Space Center, FL 32899. *Telephone:* 321–867–7214; *Facsimile:* 321–867–1817.

FOR FURTHER INFORMATION CONTACT: Randall M. Heald, Patent Counsel, Office of the Chief Counsel, Mail Code CC–A, NASA John F. Kennedy Space Center, Kennedy Space Center, FL 32899. *Telephone:* 321–867–7214; *Facsimile:* 321–867–1817. Information about other NASA inventions available for licensing can be found online at *http://techtracs.nasa.gov/*.

Dated: November 5, 2008.

Michael C. Wholley,

General Counsel.

[FR Doc. E8–26826 Filed 11–10–08; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

Notice of Applications and Amendments to Facility Operating Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information or Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information or Safeguards Information

I. Background

Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rulemaking, Directives and Editing 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 6D44, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, person(s) 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 via electronic submission through the NRC E-Filing system 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 person(s) should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland, or at *http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/part002–0309.html.* Publicly available records will be accessible 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.html.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, 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 general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include 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/requestor to relief. A petitioner/requestor who fails to satisfy 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.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E–Filing rule, which the NRC promulgated on August 28, 2007 (72 FR 49139). The E–Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E–Filing, at least ten (10) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at *hearing.docket@nrc.gov,* or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E–Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html.* Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.*

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E–Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E–Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/ehd_proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this amendment action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–

4209, (301) 415–4737 or by e-mail to *pdr.resource@nrc.gov.*

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Date of amendment request: August 1, 2008.

Description of amendment request: The amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment would revise the following: (1) Surveillance Requirement (SR) 3.5.1.4, Accumulators, and SR 3.5.4.3, Refueling Water Storage Tank, to specify three discrete levels of boron concentrations (Level 1, 2, or 3), (2) Technical specification (TS) 4.2.1, Fuel Assemblies, to increase the maximum number of Tritium Producing Burnable Absorber Rods (TPBARs) that can be irradiated per cycle from 400 to 2304, and (3) TS 5.9.5, Core Operating Limits Report (COLR), to indicate that the cycle specific boron concentrations (Level 1, 2, or 3) are specified in the COLR.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

a. Boron Concentration

The proposed change modifies the required boron concentration for the Cold Leg Accumulators (CLAs) and RWST [refueling water storage tank]. The proposed values have been verified to maintain the required accident mitigation safety function for the CLAs and RWST. The CLAs and RWST safety function is to mitigate accidents that require the injection of borated water to cool the core and to control reactivity. These functions are not potential sources for accident generation and the modification of the boron concentration that supports event mitigation will not increase the potential for an accident. Therefore, the possibility of an accident is not increased by the proposed changes. The minimum boron levels are based on the specific requirements of the core design. For each reload core design, the boron level required for subcriticality will be specified. Since the boron levels will continue to maintain the safety function of the CLAs and RWST in the same manner as currently approved, the consequences of an accident are not increased by the proposed changes.

The increase in the number of TPBARs does not adversely affect reactor neutronics or thermal-hydraulic performance; therefore, they do not significantly increase the probability of accidents or equipment malfunctions while in the reactor. The neutronic behavior of the TPBARs mimics that of standard burnable absorbers with only slight differences which are accommodated in the core design. The reload safety analysis performed for Watts Bar Unit 1 prior to each refueling cycle will confirm that any minor effects due to TPBARs on the reload core will be within fuel design limits. Analysis has shown that TPBARS are not expected to fail during Condition I through III events. TPBARs may fail during a large break LOCA or as a result of a fuel handling accident. However, the radiological consequences of these events are within 10 CFR 100 limits.

b. RCCA [Rod Cluster Control Assemblies] Insertion

WBN Unit 1 proposes to credit RCCA insertion of negative reactivity for criticality control during the core cooling flow path realignment from cold leg recirculation to hot leg recirculation following the postulated cold leg LOCA [loss-of-coolant accident]. No physical modifications will be made to plant systems, structures, or components.

Credit for RCCA insertion is only being applied to demonstrate core subcriticality upon hot leg switchover (HLSO) following a cold leg LOCA. The performance criteria codified in 10 CFR 50.46 continues to be met. The ability of the RCCAs to insert under cold leg LOCA and seismic conditions is based on analysis given in WCAP–16932–P performed by Westinghouse [Electric Company LLC]. These analyses address reactor vessel component structural distortion in a LOCA environment coincident with a seismic event. The results indicated that RCCA guide tube deflection, fuel assembly grid distortion, and displacement of the control rod driveline and CRDM supports will not preclude RCCA insertion following a cold leg LOCA.

No physical modifications will be made to plant systems, structures, or components in order to implement the proposed methodology change. The safety functions of the safety related systems and components, which are related to accident mitigation, have not been altered. Therefore, the reliability of RCCA insertion is not affected. As such, taking credit for RCCA insertion does not alter the probability of a cold leg LOCA (the design basis accident at issue). The Westinghouse analyses provided in Enclosure 5 and 6 of the application demonstrate that RCCA insertion will occur, with substantial margin, following a design basis cold leg LOCA combined with a seismic event. Crediting RCCA insertion does not affect mechanisms for a malfunction that could impact the HLSO subcriticality analysis, or mechanisms that could initiate a LOCA.

Taking credit for the negative reactivity available from insertion of the RCCAs, which is currently assumed for various accident analyses within the WBN Unit 1 licensing basis (e.g., small break LOCA, main steamline break, feedline break, steam generator tube rupture), does not affect equipment malfunction probability directly or indirectly. Therefore, crediting the RCCAs as a source of negative reactivity for post-LOCA criticality control at the time of HLSO does not significantly increase the probability of an accident previously evaluated.

Furthermore, the traditional conservative assumption that the most reactive RCCA is stuck fully out of the core is being maintained. A malfunction that results in one RCCA to fail to insert is a credible scenario, and is being considered for the post-LOCA subcriticality analysis following a cold leg LOCA. There will be sufficient negative reactivity, even with the most reactive RCCA stuck fully out of the core, to assure core subcriticality post-LOCA, as supported by the subcriticality analysis that is confirmed each and every fuel cycle as part of the reload documentation (i.e., the Reload Safety Evaluations). The core is shown to remain subcritical during the post-LOCA long-term cooling period, specifically while HLSO is performed. Thus, no additional radiological source terms are generated and the consequences of an accident previously evaluated in the UFSAR will not be significantly increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

a. Boron Concentration

The proposed change of boron concentrations for the CLAs and RWST does not have a potential to generate accidents as they only serve to perform mitigation functions associated with an accident. The proposed requirements will maintain the mitigation function in an identical manner as currently approved. There is no plant equipment or operational changes associated with the proposed revision other than the adjustment of the boron level in the CLAs and RWST.

The TPBARS have been designed to be compatible with existing Westinghouse 17 x 17 fuel assemblies and conventional Burnable Poison Rod Assembly (BPRA) handling tools, equipment, and procedures, and therefore, no new accidents or equipment malfunctions are created by the handling of TPBARS.

Therefore, since the CLA and RWST functions are not altered and the plant will continue to operate with compatible components, the possibility of a new or different kind of an accident is not created.

b. RCCA Insertion

The proposed change involves crediting the negative reactivity that is available from the RCCAs for an analysis applicable several hours after the initiation of a cold leg LOCA. As such, this change involves post-LOCA recovery actions several hours after the break has occurred and, therefore, does not involve accident initiation. As discussed above, Westinghouse analyses demonstrated that the RCCAs will insert following a cold leg LOCA with seismic loadings. Thus, the safety functions of safety related systems and components have not been altered by this change. Crediting the negative reactivity that is available from the RCCAs for the post-LOCA subcriticality analysis upon HLSO does not cause the initiation of any accident,

nor does the proposed activity create any new credible limiting single failure. Crediting the insertion of RCCAs does not result in any event previously deemed incredible being made credible nor is there any introduction of any new failure mechanisms that are not currently considered in the design basis LOCA. There are no changes introduced by this amendment concerning how safety related equipment is designed to operate under normal or design basis accident conditions since the calculations supporting RCCA insertion following a cold leg LOCA have assumed design basis break sizes in conjunction with seismic loadings.

Therefore, the possibility of an accident of a different type than already evaluated in the UFSAR is not created.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

a. Boron Concentration

This change proposes boron concentration requirements that support the accident mitigation functions of the CLAs and RWST equivalent to the currently approved limits. The proposed change does not alter any plant equipment or components and does not alter any setpoints utilized for the actuation of accident mitigation system or control functions. The proposed boron values have been verified to provide an adequate level of reactivity control for accident mitigation.

TPBARs have been designed to be compatible with existing fuel assemblies, TPBARs do not adversely affect reactor neutronic or thermal-hydraulic performance. Analysis indicates that reactor core behavior and offsite doses remain relatively unchanged.

b. RCCA Insertion

Presently, no credit is taken for RCCA insertion in the analysis to demonstrate post-cold leg LOCA subcriticality at the time of HLSO. The current subcriticality analysis for this scenario relies only on the boron provided by the RWST and the accumulators. Thus, RCCA insertion provides another source of negative reactivity (margin of safety). Revising the post-LOCA subcriticality analysis to credit the negative reactivity associated with the RCCAs is a means to offset the reactivity penalty due to potential TPBAR failures and sump dilution at the time of hot leg switchover. The incorporation of this ''defense-in-depth'' source of negative reactivity in the HLSO subcriticality analysis has been conservatively determined to not cause a reduction in the margin of safety. 10 CFR 50, Appendix K, I.A.2., states, in part, that ''[r]od trip and insertion may be assumed if they are calculated to occur,'' and provides for crediting RCCA insertion as an acceptable feature of emergency core cooling system (ECCS) evaluation models. The proposed change is based upon an analysis for WBN Unit 1 that demonstrates that the control rods will indeed insert and the resulting negative reactivity can be credited for post-LOCA criticality control.

The proposed change would ensure that post-LOCA subcriticality is maintained during HLSO. Subsequently, there would not be a challenge to long-term core cooling due to a return to a critical condition. This being the case, the requirements of 10 CFR 50,46(b)(5) that, ''* * * the calculated core temperature shall be maintained at an acceptably low value and decay heat shall be removed for the extended period of time * * *'' continues to be satisfied and the margin of safety in the WBN licensing basis is preserved.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, TVA concludes that the proposed amendment does not involve a significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and accordingly, a finding of ''no significant hazards consideration'' is justified.

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.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Branch Chief: L. Raghavan.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information (SUNSI) and Safeguards Information (SGI) for Contention Preparation

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

1. This order contains instructions regarding how potential parties to the proceedings listed above may request access to documents containing sensitive unclassified information (SUNSI and SGI).

2. Within ten (10) days after publication of this notice of opportunity for hearing, any potential party as defined in 10 CFR 2.4 who believes access to SUNSI or SGI is necessary for a response to the notice may request access to SUNSI or SGI. A ''potential party'' is any person who intends or may intend to participate as a party by demonstrating standing and the filing of an admissible contention under 10 CFR 2.309. Requests submitted later than ten (10) days will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

3. The requester shall submit a letter requesting permission to access SUNSI and/or SGI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852. The e-mail address for the Office of the Secretary and the Office of the General Counsel are *hearing.docket@nrc.gov* and *ogcmailcenter.resource@nrc.gov*, respectively.[1] The request must include the following information:

a. A description of the licensing/enforcement action with a citation to this **Federal Register** notice of hearing/notice of opportunity for hearing;

b. The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in (a)/if the enforcement action is not sustained;

c. If the request is for SUNSI, the identity of the individual requesting access to SUNSI and the requester's need for the information in order to meaningfully participate in this adjudicatory proceeding, particularly why publicly available versions of the application would not be sufficient to provide the basis and specificity for a proffered contention;

d. If the request is for SGI, the identity of the individual requesting access to SGI and the identity of any expert, consultant or assistant who will aid the requester in evaluating the SGI, and information that shows:

(i) Why the information is indispensable to meaningful participation in this licensing proceeding; and

(ii) The technical competence (demonstrable knowledge, skill, experience, training or education) of the requester to understand and use (or evaluate) the requested information to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a qualified expert, consultant or assistant who demonstrates technical competence as well as trustworthiness and reliability, and who agrees to sign a non-disclosure affidavit and be bound by the terms of a protective order; and

e. If the request is for SGI, Form SF–85, ''Questionnaire for Non-Sensitive Positions,'' Form FD–258 (fingerprint card), and a credit check release form completed by the individual who seeks access to SGI and each individual who

[1] See footnote 6. While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI and/or SGI under these procedures should be submitted as described in this paragraph.

will aid the requester in evaluating the SGI. For security reasons, Form SF–85 can only be submitted electronically, through a restricted-access database. To obtain online access to the form, the requester should contact the NRC's Office of Administration at 301–415–0320.[2] The other completed forms must be signed in original ink, accompanied by a check or money order payable in the amount of $191.00 to the U.S. Nuclear Regulatory Commission for each individual, and mailed to the: Office of Administration, Security Processing Unit, Mail Stop T–6E46, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0012.

These forms will be used to initiate the background check, which includes fingerprinting as part of a criminal history records check. **Note:** copies of these forms do *not* need to be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as described above.

4. To avoid delays in processing requests for access to SGI, all forms should be reviewed for completeness and accuracy (including legibility) before submitting them to the NRC. Incomplete packages will be returned to the sender and will not be processed.

5. Based on an evaluation of the information submitted under items 2 and 3.a through 3.d, above, the NRC staff will determine within ten days of receipt of the written access request whether (1) there is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding, and (2) there is a legitimate need for access to SUNSI or need to know the SGI requested. For SGI, the need to know determination is made based on whether the information requested is necessary (i.e., indispensable) for the proposed recipient to proffer and litigate a specific contention in this NRC proceeding[3] and whether the proposed recipient has the technical competence (demonstrable knowledge, skill, training, education, or experience) to evaluate and use the specific SGI requested in this proceeding.

6. If standing and need to know SGI are shown, the NRC staff will further determine based upon completion of the background check whether the proposed recipient is trustworthy and reliable. The NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection systems are sufficient to protect SGI from inadvertent release or disclosure. Recipients may opt to view SGI at the NRC's facility rather than establish their own SGI protection program to meet SGI protection requirements.

7. A request for access to SUNSI or SGI will be granted if:

a. The request has demonstrated that there is a reasonable basis to believe that a potential party is likely to establish standing to intervene or to otherwise participate as a party in this proceeding;

b. The proposed recipient of the information has demonstrated a need for SUNSI or a need to know for SGI, and that the proposed recipient of SGI is trustworthy and reliable;

c. The proposed recipient of the information has executed a Non-Disclosure Agreement or Affidavit and agrees to be bound by the terms of a Protective Order setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI and/or SGI; and

d. The presiding officer has issued a protective order concerning the information or documents requested.[4] Any protective order issued shall provide that the petitioner must file SUNSI or SGI contentions 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.

8. If the request for access to SUNSI or SGI is granted, the terms and conditions for access to sensitive unclassified information will be set forth in a draft protective order and affidavit of non-disclosure appended to a joint motion by the NRC staff, any other affected parties to this proceeding,[5] and the petitioner(s). If the diligent efforts by the relevant parties or petitioner(s) fail to result in an agreement on the terms and conditions for a draft protective order or non-disclosure affidavit, the relevant parties to the proceeding or the petitioner(s) should notify the presiding officer within ten (10) days, describing the obstacles to the agreement.

9. If the request for access to SUNSI is denied by the NRC staff or a request for access to SGI is denied by NRC staff either after a determination on standing and need to know or, later, after a determination on trustworthiness and reliability, the NRC staff shall briefly state the reasons for the denial. Before the Office of Administration makes an adverse determination regarding access, the proposed recipient must be provided an opportunity to correct or explain information. The requester may challenge the NRC staff's adverse determination with respect to access to SUNSI or with respect to standing or need to know for SGI by filing a challenge within ten (10) days of receipt of that determination with (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to § 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer. In the same manner, an SGI requester may challenge an adverse determination on trustworthiness and reliability by filing a challenge within fifteen (15) days of receipt of that determination.

In the same manner, a party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within ten (10) days of the notification by the NRC staff of its grant of such a request.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[6]

[2] The requester will be asked to provide his or her full name, social security number, date and place of birth, telephone number, and e-mail address. After providing this information, the requester usually should be able to obtain access to the online form within one business day.

[3] Broad SGI requests under these procedures are thus highly unlikely to meet the standard for need to know; furthermore, staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requester's need to know than ordinarily would be applied in connection with an already-admitted contention.

[4] If a presiding officer has not yet been designated, the Chief Administrative Judge will issue such orders, or will appoint a presiding officer to do so.

[5] Parties/persons other than the requester and the NRC staff will be notified by the NRC staff of a favorable access determination (and may participate in the development of such a motion and protective order) if it concerns SUNSI and if the party/person's interest independent of the proceeding would be harmed by the release of the information (e.g., as with proprietary information).

[6] As of October 15, 2007, the NRC's final ''E-Filing Rule'' became effective. See Use of Electronic Submissions in Agency Hearings (72 FR 49139; Aug. 28, 2007). Requesters should note that the

10. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI and/or SGI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those intervenors/petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR Part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

Dated at Rockville, Maryland, this 3rd day of November 2008.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI) AND SAFEGUARDS INFORMATION (SGI) IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice/other notice of proposed action and opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to SUNSI and/or SGI with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding; demonstrating that access should be granted (e.g., showing technical competence for access to SGI); and, for SGI, including application fee for fingerprint/background check.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 answers to petition for intervention; +7 petitioner/requestor reply).
20	NRC staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI or (2) need to know for SGI. (For SUNSI, NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections.
25	If NRC staff finds no ''need,'' ''need to know,'' or likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
190	(Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-disclosure Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). **Note:** Before the Office of Administration makes an adverse determination regarding access, the proposed recipient must be provided an opportunity to correct or explain information.
205	Deadline for petitioner to seek reversal of a final adverse NRC staff determination either before the presiding officer or another designated officer.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI and/or SGI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
B	Decision on contention admission.

filing requirements of that rule apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI/SGI requests submitted to the NRC staff under these procedures.

[FR Doc. E8–26716 Filed 11–10–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Availability of an Updated Version of the Guidance for Electronic Submissions to the NRC

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of availability.

SUMMARY: The latest revision of the Guidance for Electronic Submissions to the NRC (Revision 4) is now available for review. The document can be found under Submittal Instructions at *http://www.nrc.gov/site-help/e-submittals.html.* There are two significant changes to this document that are of interest to stakeholders. The first change covers the recommended file size for documents submitted to the NRC via the Electronic Information Exchange (EIE). In the past, the NRC suggested that the file size be limited to no more than 50 megabytes (MB). Based on operational experience, the NRC is modifying that recommendation and now suggests that files sent electronically to the NRC be no more than 15 MB. This revised guidance is intended to address issues that have arisen because of file size limitations

and time-out problems associated with submitter's internet service providers. The second major change is to provide information regarding a new Meta-System Help Desk, which is being established to handle specific questions about electronic filing and portable document format (PDF) creation associated with general or adjudicatory (E-Filing) submissions, as well as to provide information regarding the various components of the agency's adjudicatory information technology/information management infrastructure, including the Licensing Support Network, the Electronic Hearing Docket, and the Digital Data Management System. The new Meta-System Help Desk, which will open on November 10, 2008, will operate on weekdays (excluding Federal Holidays) between 8 a.m. and 8 p.m. Eastern Time. The Meta-System Help Desk can be contacted by telephone at 1–866–672–7640 or by e-mail at *MSHD.Resource@nrc.gov.* The Public Document Room staff, which previously responded to EIE questions, is still available to answer general questions about accessing agency documents within ADAMS or on the NRC's public Web site.

FOR FURTHER INFORMATION CONTACT: For questions about the Guidance document: Thomas Smith, Information Management Specialist, Information and Records Services Division, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–7043; *e-mail: thomas.smith@nrc.gov.* For questions about the *Meta-System Help Desk:* Ron Deavers, Project Manager, Business Process and Project Management Branch, Business Process Improvement and Applications Division, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Telephone:* 301–415–7301; *e-mail: ron.deavers@nrc.gov.*

SUPPLEMENTARY INFORMATION: Documents related to this guidance, are available electronically at the NRC's Electronic Submittals Web page at *http://www.nrc.gov/site-help/e-submittals.html.*

Dated at Rockville, MD this 5th day of November 2008.

For the Nuclear Regulatory Commission.

Joseph J. Holonich,

Director, Information and Records Services Division, Office of Information Services.

[FR Doc. E8–26805 Filed 11–10–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 040–01957 (Terminated)]

Notice of Completion of Remediation at the Homer Laughlin China Co. Site In Newell, WV

AGENCY: United States Nuclear Regulatory Commission (NRC).

ACTION: Notice of Completion of Remediation at the Homer Laughlin China Co. site in Newell, West Virginia.

FOR FURTHER INFORMATION CONTACT: John Nicholson, Health Physicist, Decommissioning Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, PA 19406; telephone 610–337–5236; fax number 610–337–5269 or by *e-mail: john.nicholson@nrc.gov.*

Background

The Homer Laughlin China Company (HLC) operates on the banks of the Ohio River in Newell, West Virginia, located in the state's northern panhandle. HLC's 37-acre site contains a number of plant buildings and structures used in the production of commercial and retail tableware.

In 1959, the NRC's Predecessor agency, the Atomic Energy Commission (AEC) issued License No. SUB–81 authorizing possession at the site of 100,000 pounds of source material for use as a glazing agent (up to 20% uranium) in the production of ceramic tableware. The finished glazed ceramic tableware products were exempt from licensing requirements. The AEC license was terminated in 1972, based upon an HLC letter stating that all remaining licensed materials had been returned to their supplier. A routine review of the terminated license file by the Oak Ridge National Laboratory (ORNL), under contract to the NRC, later determined that there was no record of a licensee closeout survey or any confirmatory survey. Based on the terminated license's possession limit and the results of the ORNL review, the NRC determined that a further assessment of HLC's site for residual radioactivity was needed.

Thus, in 1994, it was found that approximately 500 pounds of depleted uranium oxide (U_3O_8) sand was still on HLC's site. A contractor was hired to survey areas where licensed materials were used and stored, and to provide a radiological characterization of the site. Several additional areas of fixed and removable contamination exceeding NRC guidelines for unrestricted use were identified during the characterization survey. The HLC committed to package and dispose of the bulk source material, limit access to contaminated areas, and submit a decommissioning plan (DP). The NRC approved the DP in 1995, and HLC and its contractor began implementing the DP.

Discussion

The HLC did not complete decommissioning in some of the production areas because it was unable to remove fixed contamination (which exceeded NRC unrestricted release guidelines) from surfaces of equipment and structures using conventional remediation techniques. After consultation with NRC, HLC developed a risk assessment to demonstrate that the residual fixed contamination would meet the NRC release criteria. At various times during the period 1996–2004, HLC provided additional information to NRC refining its computer-based risk analysis, to demonstrate that the regulatory standard of 25 mrem/yr for unrestricted release (established in 10 CFR Part 20, Subpart E in 1997) would be met.

In March 2005, the NRC accepted HLC's revised risk assessment (ML043090164). The NRC determined that this analysis would be acceptable, pending removal of all radioactive waste from the site and review of the final survey results from the waste storage area. The uranium oxide sand and the waste material from decommissioning activities remained on site until final disposal options could be assessed. The materials were packaged and were stored in a posted and infrequently-used area of the plant. After further characterization of the waste was performed and cost estimates for disposal were obtained, HLC arranged for disposal of the waste. The waste was removed in July 2008, and sent to Waste Control Specialists, Inc. (WCS) in Texas. The waste storage area was surveyed after the waste was removed. An NRC inspector observed the waste removal and radiological survey activities. The survey results were forwarded to the NRC in September 2008. NRC staff reviewed the survey results and performed independent, bounding calculations that demonstrated that the dose rate to a worker from potential residual activity would be less than the 25 millirem/year unrestricted release standard.

Conclusion

Based on the above, the NRC staff finds that a reasonable effort had been made by HLC to eliminate residual radioactive contamination at its site and that NRC regulatory requirements are

satisfied. The NRC thus concludes that: (1) Radioactive material above release limits has been properly disposed; (2) reasonable effort has been made to eliminate residual radioactive contamination; and (3) surveys and associated documentation, demonstrate that the site meets the requirements for unrestricted release set forth in 10 CFR Part 20, Subpart E.

Further Information: Additional relevant information is available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency-wide 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* (ML043090164, ML072430077, ML072950154, ML073541298, ML080320468, ML082820580). 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.* The PDR reproduction contractor will copy documents for a fee.

Dated King of Prussia, Pennsylvania this 3rd day of November 2008.

For the Nuclear Regulatory Commission.

Raymond Lorson,

Chief, Decommissioning Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E8–26806 Filed 11–10–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide: Issuance, Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Draft Regulatory Guide, DG–1187.

FOR FURTHER INFORMATION CONTACT: Jacob Philip, U. S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *telephone:* (301) 415–6211 or e-mail to *Jacob.Philip@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) has issued for public comment a draft regulatory guide in the agency's ''Regulatory Guide'' series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), titled, ''Concrete Radiation Shields and Generic Shield Testing for Nuclear Power Plants,'' is temporarily identified by its task number, DG–1187, which should be mentioned in all related correspondence. DG–1187 is proposed Revision 1 of Regulatory Guide 1.69.

This guide describes a method that the staff of the NRC considers acceptable for use in complying with the regulations for concrete radiation shields for nuclear power plants.

As stated in Title 10, Section 20.1201, ''Occupational Dose Limits for Adults,'' of the Code of Federal Regulations (10 CFR 20.1201), licensees shall control the occupational dose to individual adults to the limits stated therein. Furthermore, 10 CFR 20.1101(b) provides that licensees shall use, to the extent practicable, procedures and engineering controls based upon sound radiation principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable. General Design Criterion 1, ''Quality Standards and Records,'' of Appendix A, ''Quality Design Criteria for Nuclear Power Plants,'' to 10 CFR part 50, ''Licensing of Production and Utilization Facilities,'' requires that structures, systems, and components important to safety be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety function to be performed. Appendix B, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50 requires that measures be established to ensure design control and inspection and test controls. Appendix B also requires that activities affecting quality be accomplished under suitably controlled conditions. This guide describes some bases acceptable to the NRC staff for implementing the above requirements with regard to the design and construction of concrete radiation shields in nuclear power plants.

II. Further Information

The NRC staff is soliciting comments on DG–1187. Comments may be accompanied by relevant information or supporting data, and should mention DG–1187 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Personal information will not be removed from your comments. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

2. *E-mail comments to: nrcrep.resource@nrc.gov.*

3. *Hand-deliver comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

4. *Fax comments to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 415–5144.

Requests for technical information about DG–1187 may be directed to Jacob Philip at (301) 415–6211 or e-mail to *Jacob.Philip@nrc.gov.*

Comments would be most helpful if received by January 9, 2009. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG–1187 are available through the NRC's public Web site under Draft Regulatory Guides in the ''Regulatory Guides'' collection of the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/doc-collections/.* Electronic copies are also available in ADAMS (*http://www.nrc.gov/reading-rm/adams.html*), under Accession No. ML082190117.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 5th day of November, 2008.

For the Nuclear Regulatory Commission.

Harriet Karagiannis,

Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. E8–26804 Filed 11–10–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Weeks of November 10, 17, 24, December 1, 8, 15, 2008.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 10, 2008

There are no meetings scheduled for the week of November 10, 2008.

Week of November 17, 2008—Tentative

There are no meetings scheduled for the week of November 17, 2008.

Week of November 24, 2008—Tentative

There are no meetings scheduled for the week of November 24, 2008.

Week of December 1, 2008—Tentative

There are no meetings scheduled for the week of December 1, 2008.

Week of December 8, 2008—Tentative

Tuesday, December 9, 2008

9:30 a.m.
Briefing on Equal Employment Opportunity (EEO) Programs (Public Meeting) (Contact: Sandy Talley, 301–415–8059).
This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Thursday, December 11, 2008

9:30 a.m.
Briefing on Uranium Recovery—Part 1 (Public Meeting).
1:30 p.m.
Briefing on Uranium Recovery—Part 2 (Public Meeting).
(*Contact for both parts:* Dominick Orlando, 301–415–6749). Both parts of this meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Friday, December 12, 2008

9:30 a.m.
Discussion of Management Issues (Closed—Ex. 2).

Week of December 15, 2008—Tentative

Monday, December 15, 2008

1 p.m.
Discussion of Management Issues (Closed—Ex. 2).

Wednesday, December 17, 2008

2 p.m.
Briefing on Threat Environment Assessment (Closed—Ex. 1).

* * * * *

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html*.

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This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *darlene.wright@nrc.gov*.

Dated: November 6, 2008.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. E8–26921 Filed 11–7–08; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58897; File No. SR–NASDAQ–2008–018]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Approving Proposed Rule Change as Modified by Amendment Nos. 1 and 2 Thereto to Remove from Rule 7019 the Fees for Receiving Index Values

November 3, 2008.

On March 12, 2008, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to remove from the Nasdaq rulebook references to the fees charged by Nasdaq for receiving index values. On September 5, 2008, Nasdaq filed Amendment No. 1 to the proposed rule change. On September 25, 2008, Nasdaq filed Amendment No. 2 to the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on October 3, 2008.[3] The Commission received no comments regarding the proposal. This order approves the proposed rule change, as modified by Amendment Nos. 1 and 2.

Nasdaq distributes values for indexes and exchange traded funds (''ETFs'') through an index dissemination service. Through this service, Nasdaq calculates and disseminates the values of Nasdaq indexes, such as the Nasdaq-100, and, on occasion, non-Nasdaq indexes. Nasdaq also distributes information related to ETFs, including intra-day asset values. All market participants may subscribe to the index dissemination service.

Nasdaq Rule 7019(b) sets forth the fees paid by distributors to receive various Nasdaq Market Center data feeds. Nasdaq proposes to delete the portion of Rule 7019(b) that relates to fees for the index dissemination service.

The Commission has carefully reviewed the proposed rule change and finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[4] The Commission believes that it is reasonable for Nasdaq

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 58666 (September 26, 2008), 73 FR 57725.

[4] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

to delete the portion of Rule 7019(b) that relates to fees for the index dissemination service, as, based on representations made by Nasdaq, the index dissemination service does not appear to be a facility of a national securities exchange within the meaning of the Act. Removing the provisions of Rule 7019(b) that relate to the index dissemination service is thus consistent with the requirements of section 6(b) of the Act,[5] as the fees charged by Nasdaq in connection with the index dissemination service do not fall within the scope of the rules that must be filed with the Commission pursuant to section 19(b)(1) of the Act[6] and Rule 19b–4 thereunder.[7]

If, however, Nasdaq were to propose to tie pricing for the index dissemination service to exchange services, or otherwise modify the index dissemination service such that it falls within the definition of facility of an exchange in the Act,[8] Nasdaq would have to file a proposed rule change with the Commission. Similarly, Nasdaq would have to file a proposed rule change with the Commission if it were to condition a company's inclusion in an index on that company's listing market.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–NASDAQ–2008–018), as modified by Amendment Nos. 1 and 2, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26625 Filed 11–10–08; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78s(b)(1).

[7] 17 CFR 240.19b–4.

[8] *See* 15 U.S.C. 78c(a)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58894; File No. SR–NASDAQ–2008–086]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Extend the Pilot Program for NASDAQ Last Sale Data Feeds

October 31, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2008, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend for two months the four-month pilot that created the NASDAQ Last Sale (''NLS'') market data products. NLS allows data distributors to have access to real-time market data for a capped fee, enabling those distributors to provide free access to the data to millions of individual investors via the internet and television. Specifically, NASDAQ offers the ''NASDAQ Last Sale for NASDAQ'' and ''NASDAQ Last Sale for NYSE/Amex'' data feeds containing last sale activity in U.S. equities within the NASDAQ Market Center and reported to the jointly-operated FINRA/NASDAQ Trade Reporting Facility (''FINRA/NASDAQ TRF'').

This pilot program supports the aspiration of Regulation NMS to increase the availability of proprietary data by allowing market forces to determine the amount of proprietary market data information that is made available to the public and at what price. During the current pilot period, the program has vastly increased the availability of NASDAQ proprietary market data to individual investors. Based upon data from NLS distributors, NASDAQ believes that since its launch in July 2008, the NLS data has been viewed by over 50,000,000 investors on websites operated by Google, Interactive Data, and Dow Jones, among others. The text of the proposed rule change is available at NASDAQ, the Commission's Public Reference Room, and *http://nasdaq.complinet.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Prior to the launch of NLS, public investors that wished to view market data to monitor their portfolios generally had two choices: (1) Pay for real-time market data or (2) use free data that is 15 to 20 minutes delayed. To increase consumer choice, NASDAQ proposed a four-month pilot to offer access to real-time market data to data distributors for a capped fee, enabling those distributors to disseminate the data via the internet and television at no cost to millions of internet users and television viewers. NASDAQ now proposes a two-month extension of that pilot program asset forth in the original proposal as described below.

The NLS pilot created two separate ''Level 1'' products containing last sale activity within the NASDAQ market and reported to the jointly-operated FINRA/NASDAQ TRF. First, the ''NASDAQ Last Sale for NASDAQ Data Product,'' a real-time data feed that provides real-time last sale information including execution price, volume, and time for executions occurring within the NASDAQ system as well as those reported to the FINRA/NASDAQ TRF. Second, the NASDAQ Last Sale for NYSE/Amex data product that provides real-time last sale information including execution price, volume, and time for NYSE- and Amex-securities executions occurring within the NASDAQ system as well as those reported to the FINRA/NASDAQ TRF.

NASDAQ developed these product proposals in consultation with industry members and also market data vendors and purchasers. These products are designed to meet the needs of current and prospective subscribers that do not need or are unwilling to pay for the consolidated data provided by the SIP Level 1 products. NASDAQ is also proposing to ease the administrative burden of market data vendors that are receiving and using data in new ways, particularly those that provide the data via the internet and various television media. Providing investors with new options for receiving market data was a primary goal of the market data

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

amendments adopted in Regulation NMS.

NASDAQ established two different pricing models, one for clients that are able to maintain username/password entitlement systems and/or quote counting mechanisms to account for usage, and a second for those that are not. Firms with the ability to maintain username/password entitlement systems and/or quote counting mechanisms will be eligible for a specified fee schedule for the NASDAQ Last Sale for NASDAQ Product and a separate fee schedule for the NASDAQ Last Sale for NYSE/Amex Product: Firms that were unable to maintain username/password entitlement systems and/or quote counting mechanisms will also have multiple options for purchasing the NASDAQ Last Sale data. These firms chose between a ''Unique Visitor'' model for internet delivery or a ''Household'' model for television delivery. Unique Visitor and Household populations must be reported monthly and must be validated by a third-party vendor or ratings agency approved by NASDAQ at NASDAQ's sole discretion. In addition, to reflect the growing confluence between these media outlets, NASDAQ offered a reduction in fees when a single distributor distributes NASDAQ Last Sale Data Products via multiple distribution mechanisms. Finally, NASDAQ established cap of $100,000 per month for NASDAQ Last Sale for NASDAQ and $50,000 per month for NASDAQ Last Sale for NYSE/Amex. NASDAQ believed that it is reasonable and appropriate to benefit small and medium-sized vendors by proposing a progressive fee schedule and to benefit large vendors by proposing to cap the monthly fees.

As with the distribution of other NASDAQ proprietary products, all distributors of the NASDAQ Last Sale for NASDAQ and/or NASDAQ Last Sale for NYSE/Amex products would pay a single $1500/month NASDAQ Last Sale Distributor Fee in addition to any applicable usage fees. The $1,500 monthly fee will apply to all distributors and will not vary based on whether the distributor distributes the data internally or externally or distributes the data via both the internet and television.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of section 6 of the Act,[3] in general and with section 6(b)(4) of the Act,[4] as stated above, in that it provides an equitable allocation of reasonable fees among users and recipients of NASDAQ data. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

The NASDAQ Last Sale market data products proposed here appear to be precisely the sort of market data product that the Commission envisioned when it adopted Regulation NMS. The Commission concluded that Regulation NMS-by deregulating the market in proprietary data-would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[5]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether, proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well.

NASDAQ's ability to price its Last Sale Data Products is constrained by (1) competition between exchanges and other trading platforms that compete with each other in a variety of dimensions; (2) the existence of inexpensive real-time consolidated data and free delayed consolidated data, and (3) the inherent contestability of the market for proprietary last sale data.

The market for proprietary last sale data products is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market.

Broker-dealers currently have numerous alternative venues for their order flow, including eleven self-regulatory organization (''SRO'') markets, as well as broker-dealers (''BDs'') and aggregators such as the BATS electronic communications network (''ECN''). Each SRO market competes to produce transaction reports via trade executions, and an ever-increasing number of FINRA-regulated Trade Reporting Facilities (''TRFs'') compete to attract internalized transaction reports. It is common for BDs to further and exploit this competition by sending their order flow and transaction reports to multiple markets, rather than providing them all to a single market. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products.

The large number of SROs, TRFs, and ECNs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ECN and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including NASDAQ, NYSE, Amex, NYSEArca, and BATS.

Any ECN or BD can combine with any other ECN, broker-dealer, or multiple ECNs or BDs to produce jointly proprietary data products. Additionally, non-broker-dealers such as order routers like LAVA, as well as market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ECNs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS does today by publishing its proprietary book data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace writ large.

Consolidated data provides two additional measures of pricing discipline for proprietary data products that are a subset of the consolidated data

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f–3(b)(4).

[5] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

stream. First, the consolidated data is widely available in real-time at $1 per month for non-professional users. Second, consolidated data is also available *at no cost* with a 15- or 20-minute delay. Because consolidated data contains marketwide information, it effectively places a cap on the fees assessed for proprietary data (such as last sale data) that is simply a subset of the consolidated data. The mere availability of low-cost or free consolidated data provides a powerful form of pricing discipline for proprietary data products that contain data elements that are a subset of the consolidated data, by highlighting the optional nature of proprietary products.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end users. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only that data which will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. NASDAQ and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to successfully market proprietary data products.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN, and BATS Trading. Today, BATS publishes its data at no charge on its Web site in order to attract order flow, and it uses market data revenue rebates from the resulting executions to maintain low execution charges for its users. Several ECNs have existed profitably for many years with a minimal share of trading, including Bloomberg Tradebook and NexTrade.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, Reuters and Thomson. New entrants are already on the horizon, including ''Project BOAT,'' a consortium of financial institutions that is assembling a cooperative trade collection facility in Europe. These institutions are active in the United States and could rapidly and profitably export the Project Boat technology to exploit the opportunities offered by Regulation NMS.

In establishing the price for the NASDAQ Last Sale Products, NASDAQ considered the competitiveness of the market for last sale data and all of the implications of that competition. NASDAQ believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish a fair, reasonable, and not unreasonably discriminatory fee and an equitable allocation of fees among all users.

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. To the contrary, the NASDAQ Last Sale Products respond to and enhance competition that already exists in the market.

On May 28, 2008, the Internet portal Yahoo! announced that it would offer its Web site viewers real-time last sale data provided by BATS Trading. NASDAQ's last sale data products would compete directly with the BATS product disseminated via Yahoo! because BATS Trading has substantially less market share in NASDAQ-listed issues and its market data is less complete. Preventing NASDAQ from responding to this competition from its less-regulated competitor runs counter to the pro-competitive goals of the Act.

In addition, as set forth in detail above, the market for last sale data is already competitive, with both real-time and delayed consolidated data as well as the ability for innumerable entities begin rapidly and inexpensively to offer competitive last sale data products. Moreover, the New York and American Stock Exchanges have each proposed to distribute competing last sale data products. Under the deregulatory regime of Regulation NMS, there is no limit to the number of competing products that can be developed quickly and at low cost. The Commission should not stand in the way of enhanced competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Three comment letters were filed regarding the proposed rule change as originally published for comment. NASDAQ responded to these comments in a letter dated December 13, 2007. Both the comment letters and NASDAQ's response are available on the SEC Web site at *http://www.sec.gov/comments/sr-nasdaq-2006-060/nasdaq2006060.shtml*.

III. 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. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2008–086 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2008–086. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2008–086 and should be submitted on or before December 3, 2008.

IV. Commission's Findings and Order Granting Accelerated Approval of a Proposed Rule Change

The Commission finds that the proposed rule change, to extend the pilot program for two months, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[6] In particular, it is consistent with section 6(b)(4) of the Act,[7] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other parties using its facilities, and section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission also finds that the proposed rule change is consistent with the provisions of section 6(b)(8) of the Act,[9] which requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Finally, the Commission finds that the proposed rule change is consistent with Rule 603(a) of Regulation NMS,[10] adopted under section 11A(c)(1) of the Act, which requires an exclusive processor that distributes information with respect to quotations for or transactions in an NMS stock to do so on terms that are fair and reasonable and that are not unreasonably discriminatory.[11]

The Commission approved the fee for the NASDAQ Last Sale Data Feeds for a pilot period which runs until October 31, 2008.[12] The Commission approved the fee for the NASDAQ Last Sale Data Feeds for a pilot period which runs until October 31, 2008. The Commission notes that the Exchange proposes to extend the pilot program for two months. The Exchange proposes no other changes to the existing pilot program.

On June 4, 2008, the Commission approved for public comment a draft approval order that sets forth a market-based approach for analyzing proposals by self-regulatory organizations to impose fees for ''non-core'' market data products that would encompass the NASDAQ Last Sale Data Feeds.[13] The Commission believes that the proposal is consistent with the Act for the reasons noted preliminarily in the Draft Approval Order. Pending review by the Commission of comments received on the Draft Approval Order, and final Commission action thereon, the Commission believes that approving NASDAQ's proposal to extend the pilot program that imposes a fee for the NASDAQ Last Sale Data Feeds for two months would be beneficial to investors and in the public interest, in that it should result in increased broad public dissemination of real-time pricing information. The broader approach ultimately taken by the Commission with respect to non-core market data fees will necessarily guide Commission action regarding fees for the NASDAQ Last Sale Data Feeds beyond the pilot period.

The Commission finds good cause for approving the proposed rule change before the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. Accelerating approval of this proposal should benefit investors by facilitating their access to widespread, free, real-time pricing information contained in the NASDAQ Last Sale Data Feeds. Therefore, the Commission finds good cause, consistent with Section 19(b)(2) of the Act,[14] to approve the proposed rule change on an accelerated basis to extend the operation of the pilot until December 31, 2008, while the Commission analyzes comments on the Draft Approval Order.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–NASDAQ–2008–086) is hereby approved on an accelerated basis until December 31, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26626 Filed 11–10–08; 8:45 am]

BILLING CODE 8011–01–P

[6] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] 17 CFR 242.603(a).

[11] NASDAQ is an exclusive processor of its last sale data under Section 3(a)(22)(B) of the Act, 15 U.S.C. 78c(a)(22)(B), which defines an exclusive processor as, among other things, an exchange that distributes data on an exclusive basis on its own behalf.

[12] *See* Securities Exchange Act Release No. 57965 (June 16, 2008), 73 FR 35178 (June 20, 2008) (SR–NASDAQ–2006–060).

[13] *See* Securities Exchange Act Release No. 57917 (June 4, 2008), 73 FR 32751 (June 10, 2008) (Notice of Proposed Order Approving Proposal by NYSE Arca, Inc. to Establish Fees for Certain Market Data and Request for Comment) (''Draft Approval Order'').

[14] 15 U.S.C. 78s(b)(2).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58895; File No. SR–NYSEArca–2008–122]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Extend the Pilot Program for NYSE Arca Realtime Reference Prices Service

October 31, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2008, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the expiration date of its pilot program for the NYSE Arca Realtime Reference

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Prices service until December 31, 2008. There is no new rule text.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In File No. SR–NYSEArca–2008–96, the Exchange established a pilot program that allows the Exchange to test the viability of a new NYSE Arca-only market data service that allows a vendor to redistribute on a real-time basis last sale prices of transactions that take place on the Exchange (''NYSE Arca Realtime Reference Prices'') and to establish a flat monthly fee for that service. The Commission approved that pilot program on August 29, 2008.[3]

The Exchange intends for the NYSE Arca Realtime Reference Prices service to accomplish three goals:

1. To provide a low-cost service that will make real-time prices widely available to millions of casual investors;
2. To provide vendors with a real-time substitute for delayed prices; and
3. To relieve vendors of administrative burdens.

This pilot program is similar to pilot programs that the Nasdaq Stock Market, Inc. (''Nasdaq''),[4] and the New York Stock Exchange, LLC (''NYSE''),[5] have established.

The pilot program allows internet service providers, traditional market data vendors, and others (''NYSE Arca-Only Vendors'') to make available NYSE Arca Realtime Reference Prices on a real-time basis.[6] The NYSE Arca Realtime Reference Price information includes last sale prices for all securities that trade on the Exchange. It includes only prices, and not the size of each trade and not bid/asked quotations.

It features a flat, fixed monthly vendor fee, no user-based fees, no vendor reporting requirements, and no professional or non-professional subscriber agreements.

The Exchange established November 1, 2008, as the end date for the pilot program. The Exchange now seeks to extend that end date to December 31, 2008. Prior to the end of the pilot period, the Exchange will assess its experience with the product and either will submit a proposed rule change that seeks to extend or modify the pilot program or to make it permanent, or it will announce publicly that it does not seek to extend the pilot program beyond the program's termination date.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(4)[7] that an exchange have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities and the requirements under Section 6(b)(5)[8] that the rules of an exchange be designed to promote just and equitable principles of trade and not to permit unfair discrimination between customers, issuers, brokers or dealers.

The Exchange believes that the pilot program benefits investors by facilitating their prompt access to widespread, free, real-time pricing information contained in the NYSE Arca Realtime Reference Prices service. Extending the pilot program will extend those benefits while the Exchange assesses the service.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not received any unsolicited written comments from members or other interested parties.

III. 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. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2008–122 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2008–122. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2008–122 and should be submitted on or before December 1, 2008.

IV. Commission's Findings and Order Granting Accelerated Approval of a Proposed Rule Change

The Commission finds that the proposed rule change, to extend the pilot program for two months, is

[3] *See* Securities Exchange Act Release No. 58444 (August 29, 2008), 73 FR 51872 (September 5, 2008) (SR–NYSEArca–2008–96).

[4] *See* Securities Exchange Act Release Nos. 57965 (June 16, 2008), 73 FR 35178 (June 20, 2008) (SR–NASDAQ–2006–060); 57973 (June 16, 2008), 73 FR 35430 (June 23, 2008) (SR–NASDAQ–2008–050).

[5] *See* Securities Exchange Act Release No. 57966 (June 16, 2008), 73 FR 35182 (June 20, 2008) (SR–NYSE–2007–04).

[6] The Exchange notes that it will make the NYSE Arca Realtime Reference Prices available to vendors no earlier than it makes those prices available to the processor under the CTA Plan.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[9] In particular, it is consistent with section 6(b)(4) of the Act,[10] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other parties using its facilities, and section 6(b)(5) of the Act,[11] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission also finds that the proposed rule change is consistent with the provisions of section 6(b)(8) of the Act,[12] which requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Finally, the Commission finds that the proposed rule change is consistent with Rule 603(a) of Regulation NMS,[13] adopted under section 11A(c)(1) of the Act, which requires an exclusive processor that distributes information with respect to quotations for or transactions in an NMS stock to do so on terms that are fair and reasonable and that are not unreasonably discriminatory.[14]

The Commission approved the fee for NYSE Arca Realtime Reference Prices for a pilot period which runs until October 31, 2008.[15] The Commission notes that the Exchange proposes to extend the pilot program for two months. The Exchange proposes no other changes to the existing pilot program.

On June 4, 2008, the Commission approved for public comment a draft approval order that sets forth a market-based approach for analyzing proposals by self-regulatory organizations to impose fees for ''non-core'' market data products that would encompass the NYSE Arca Realtime Reference Prices.[16] The Commission believes that the proposal is consistent with the Act for the reasons noted preliminarily in the Draft Approval Order. Pending review by the Commission of comments received on the Draft Approval Order, and final Commission action thereon, the Commission believes that approving NYSE Arca's proposal to extend the pilot program that imposes a fee for NYSE Arca Realtime Reference Prices for two months would be beneficial to investors and in the public interest, in that it should result in increased broad public dissemination of real-time pricing information. The broader approach ultimately taken by the Commission with respect to non-core market data fees will necessarily guide Commission action regarding fees for the NYSE Arca Realtime Reference Prices beyond the pilot period.

The Commission finds good cause for approving the proposed rule change before the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. Accelerating approval of this proposal should benefit investors by facilitating their access to widespread, free, real-time pricing information contained in the NYSE Arca Realtime Reference Prices. Therefore, the Commission finds good cause, consistent with Section 19(b)(2) of the Act,[17] to approve the proposed rule change on an accelerated basis to extend the operation of the pilot until December 31, 2008, while the Commission analyzes comments on the Draft Approval Order.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–NYSEArca–2008–122) is hereby approved on an accelerated basis until December 31, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26627 Filed 11–10–08; 8:45 am]

BILLING CODE 8011–01–P

[9] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78f(b)(8).

[13] 17 CFR 242.603(a).

[14] NYSE Arca is an exclusive processor of its last sale data under Section 3(a)(22)(B) of the Act, 15 U.S.C. 78c(a)(22)(B), which defines an exclusive processor as, among other things, an exchange that distributes data on an exclusive basis on its own behalf.

[15] *See supra* note 3.

[16] *See* Securities Exchange Act Release No. 57917 (June 4, 2008), 73 FR 32751 (June 10, 2008) (Notice of Proposed Order Approving Proposal by NYSE Arca, Inc. to Establish Fees for Certain Market Data and Request for Comment) (''Draft Approval Order'').

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

15th Meeting: RTCA Special Committee 206/EUROCAE WG 76 Plenary

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 206 meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 206: Aeronautical Information Services Data Link.

DATES: The meeting will be held December 9–12, 2008 from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at (training facilities), Rua C, Edificio 7, Aeroporto de Lisboa, 1700–008 Sisboa, Portugal. Hosted by: NAV Portugal, *http://www.nav.pt.*

FOR FURTHER INFORMATION CONTACT: José Resendes, *jose.resendes@nav.pt* also Ana Paula Frangolho—32–2–729 4702.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 206 meeting/EUROCE WG 76. The agenda will include:

9 December

Opening Plenary (Chairman's Remarks and Introductions, Review and Approve Meeting Agenda and Minutes, Discussion).

- Schedule for this week
- Action Item Review
- Schedule for next meetings

Presentations.

- Flight Test Campaign of FLYSAFE—Laurence Mutuel
- Action Items—Gary Livack and Kevin Mattison
- Action Items—Christian Bousmanne
- Others to be determined

SPR and INTEROP.

10 December

AIS Subgroup meeting.

Meteorology Subgroup meeting.

11 December

Subgroup 1 and Subgroup 2 meetings.

12 December

Subgroup 1 and Subgroup 2 meetings.

Closing Plenary Session (Other Business, Meeting Plans and Dates, Closing Remarks, Adjourn).

Attendance is open to the interested public but limited to space availability.

With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 5, 2008.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. E8–26845 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2008–0050]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: The Federal Transit Administration invites public comment about our intention to request the Office of Management and Budget's (OMB) approval to renew the following information collection: 49 U.S.C. section 5316—Job Access and Reverse Commute Program.

The information to be collected for this program is used to determine eligibility for funding and to monitor the grantees' progress in implementing and completing project activities. The information submitted ensures FTA's compliance with applicable federal laws and OMB Circular A–102. The **Federal Register** Notice with a 60-day comment period soliciting comments was published on September 12, 2008.

DATES: Comments must be submitted before December 12, 2008. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Sylvia L. Marion, Office of Administration, Office of Management Planning, (202) 366–6680.

SUPPLEMENTARY INFORMATION:

Title: 49 U.S.C. section 5316—Job Access and Reverse Commute Program.

Abstract: 49 U.S.C. section 5316, the Job Access and Reverse Commute (JARC) Program, authorizes the Secretary of Transportation to make grants to states for areas with a population of less than 200,000 and designated recipients in urbanized areas of 200,000 persons or greater to transport welfare recipients and other low-income individuals to and from jobs and activities related to employment. Grant recipients are required to make information available to the public and to publish a program of projects which identifies the subrecipients and projects for which the State or designated recipient is applying for financial assistance. FTA uses the information to determine eligibility for funding and to monitor the grantees' progress in implementing and completing project activities. FTA collects performance information annually from designated recipients in rural areas, small urbanized areas, other direct recipients for small urbanized areas, and designated recipients in urbanized areas of 200,000 persons or greater. FTA collects milestone and financial status reports from designated recipients in large urbanized areas on a quarterly basis. The information submitted ensures FTA's compliance with applicable federal laws and OMB Circular A–102.

Estimated Total Annual Burden: 122,374 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, *Attention:* FTA Desk Officer.

Comments Are Invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued On: October 30, 2008.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. E8–26412 Filed 11–10–08; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF THE TREASURY

Government Securities: Call for Large Position Reports

AGENCY: Office of the Assistant Secretary for Financial Markets, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury (''Department'' or ''Treasury'') called for the submission of Large Position Reports by those entities whose reportable positions in either the 2% Treasury Notes of September 2010 or the 3⅛% Treasury Notes of September 2013 equaled or exceeded $2 billion as of close of business November 6, 2008.

DATES: Large Position Reports must be received before noon Eastern Time on November 14, 2008.

ADDRESSES: The reports must be submitted to the Federal Reserve Bank of New York, Government Securities Dealer Statistical Unit, 4th Floor, 33 Liberty Street, New York, New York 10045; or faxed to 212–720–5030.

FOR FURTHER INFORMATION CONTACT: Lori Santamorena, Executive Director; Lee Grandy, Associate Director; or Kevin Hawkins, Government Securities Specialist; Bureau of the Public Debt, Department of the Treasury, at 202–504–3632.

SUPPLEMENTARY INFORMATION: In a press release issued on November 7, 2008, and in this **Federal Register** notice, the Treasury called for Large Position Reports from entities whose reportable positions in the following two securities equaled or exceeded $2 billion as of the close of business Thursday, November 6, 2008:

(1) The 2% Treasury Notes of September 2010, or

(2) The 3⅛% Treasury Notes of September 2013.

Entities whose reportable positions in either of these notes equaled or exceeded the $2 billion threshold must submit a report for that security to the Federal Reserve Bank of New York. Entities with positions in these notes below $2 billion are not required to file reports. Large Position Reports must be received by the Government Securities Dealer Statistical Unit of the Federal Reserve Bank of New York before noon Eastern Time on Friday, November 14, 2008, and must include the required positions and administrative information. The reports may be faxed to (212) 720–5030 or delivered to the Bank at 33 Liberty Street, 4th floor.

The 2% Treasury Notes of September 2010, Series AC–2010, have a CUSIP number of 912828 JL 5, a STRIPS principal component CUSIP number of 912820 RH 2, and a maturity date of September 30, 2010.

The 3⅛% Treasury Notes of September 2013, Series Q–2013, have a CUSIP number of 912828 JM 3, a STRIPS principal component CUSIP number of 912820 RJ 8, and a maturity date of September 30, 2013.

The press release and a copy of a sample Large Position Report, which appears in Appendix B of the rules at 17 CFR Part 420, are available at the Bureau of the Public Debt's Web site at *http://www.treasurydirect.gov/instit/statreg/gsareg/gsareg.htm.*

Questions about Treasury's large position reporting rules should be directed to Treasury's Government Securities Regulations Staff at Public Debt on (202) 504–3632. Questions regarding the method of submission of Large Position Reports should be directed to the Government Securities Dealer Statistical Unit of the Federal Reserve Bank of New York at (212) 720–7993.

The collection of large position information has been approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act under OMB Control Number 1535–0089.

Karthik Ramanathan,

Acting Assistant Secretary for Financial Markets.

[FR Doc. E8–26932 Filed 11–7–08; 12:00 pm]

BILLING CODE 4810–39–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0156]

Proposed Information Collection (Notice of Change in Student Status) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to report changes in students' enrollment status.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 12, 2009.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0156'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Notice of Change in Student Status (Under Chapter 30, 32, or 35, Title 38 U.S.C.; Chapters 1606 and 1607, Title 10 U.S.C.; or Section 901 and 903 of Pub. L. 96–342; the National Call to Service Provision of Public Law 107–314; the ''Transfer of Entitlement'' Provision of Pub. L. 107–107; and the Omnibus Diplomatic Security and Antiterrorism Act of 1986), VA Form 22–1999b.

OMB Control Number: 2900–0156.

Type of Review: Revision of a currently approved collection.

Abstract: Educational institutions use VA Form 22–1999b to report a student's enrollment status. Benefits are not payable when the student interrupts or terminates a program. VA uses the information to determine the student's continued entitlement to educational benefits or if the benefits should be increased, decreased, or terminated.

Affected Public: Business or other for-profit, and not-for-profit institutions.

Estimated Annual Burden: 51,667 hours.

a. VA Form 22–1999b (Paper Copy)—16,667 hours.

b. VA Form 22–1999b (Electronically Filed)—35,000 hours.

Estimated Average Burden Per Respondent:

a. VA Form 22–1999b (Paper Copy)—10 minutes.

b. VA Form 22–1999b (Electronically Filed)—7 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 8,500.

Estimated Total Number of Responses Annually: 400,000.

a. VA Form 22–1999b (Paper Copy)—100,000.

b. VA Form 22–1999b (Electronically Filed)—300,000.

Dated: November 5, 2008.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E8–26857 Filed 11–10–08; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0674]

Proposed Information Collection (Clarification of a Notice of Disagreement) Activity Comment Request

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Board of Veterans' Appeals (BVA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to clarify actions taken by the agency of original jurisdiction regarding a claimant's disagreement with his or her rating decision.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 12, 2009.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to Sue

Hamlin, Board of Veterans' Appeals (01C), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *sue.hamlin@va.gov.* Please refer to ''OMB Control No. 2900–0674'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sue Hamlin at (202) 461–8194 or fax (202) 565–5270.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, BVA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of BVA's functions, including whether the information will have practical utility; (2) the accuracy of BVA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Clarification of Notice of Disagreement.

OMB Control Number: 2900–0674.

Type of Review: Extension of a currently approved collection.

Abstract: A Notice of Disagreement (NOD) is a written communication from a claimant or his or her representative to express disagreement or dissatisfaction with the result of an adjudicative determination by the agency of original jurisdiction (AOJ). The data collected will be used by the AOJ to reexamine the issues in dispute and to determine if additional review or development is warranted.

Affected Public: Individuals or households.

Estimated Total Annual Burden: 113,539.

Estimated Average Burden Per Respondent: 1 hour.

Frequency of Response: On occasion.

Estimated Total Number of Respondents: 113,539.

Dated: November 5, 2008.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E8–26860 Filed 11–10–08; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Homeless Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Advisory Committee on Homeless Veterans will be held on December 15–16, 2008, at the Ritz Carlton New Orleans, 921 Canal Street, New Orleans, Louisiana, in room Union Terrace A. The sessions will start at 8 a.m. and end at 4 p.m. each day. The meeting is open to the public.

The purpose of the Committee is to provide the Secretary of Veterans Affairs with an on-going assessment of the effectiveness of the policies, organizational structures, and services of the Department in assisting homeless veterans. The Committee shall assemble and review information relating to the needs of homeless veterans and provide advice on the most appropriate means of offering assistance to homeless veterans. The Committee will make recommendations to the Secretary regarding such activities.

On December 15, the Committee will receive briefings from VA and other federal departments on programs and activities affecting homeless veterans. On December 16, the Committee will continue to receive informational presentations and will begin its discussion of recommendations to be included in the upcoming annual report.

Those wishing to attend the meeting should contact Mr. Pete Dougherty, Department of Veterans Affairs, at (202) 461–7401. No time will be allocated for receiving oral presentations from the public. However, the Committee will accept written comments from interested parties on issues affecting homeless veterans. Such comments should be referred to the Committee at the following address: Advisory Committee on Homeless Veterans, Homeless Veterans Programs Office (075D), U.S. Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420.

Dated: November 4, 2008.

By direction of the Secretary.

E. Philip Riggin,

Committee Management Officer.

[FR Doc. E8–26861 Filed 11–10–08; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Wednesday,
November 12, 2008

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 53, and 58
National Ambient Air Quality Standards for Lead; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 53 and 58

[EPA–HQ–OAR–2006–0735; FRL–8732–9]

RIN 2060–AN83

National Ambient Air Quality Standards for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA is making revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. With regard to the primary standard, EPA is revising the level to 0.15 μg/m^3. EPA is retaining the current indicator of Pb in total suspended particles (Pb-TSP). EPA is revising the averaging time to a rolling 3-month period with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period. EPA is revising the secondary standard to be identical in all respects to the revised primary standard.

EPA is also revising data handling procedures, including allowance for the use of Pb-PM$_{10}$ data in certain circumstances, and the treatment of exceptional events, and ambient air monitoring and reporting requirements for Pb, including those related to sampling and analysis methods, network design, sampling schedule, and data reporting. Finally, EPA is revising emissions inventory reporting requirements and providing guidance on its approach for implementing the revised primary and secondary standards for Pb.

DATES: This final rule is effective on January 12, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2006–0735. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The 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 Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For further information in general or specifically with regard to sections I through III or VIII, contact Dr. Deirdre Murphy, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504–06, Research Triangle Park, NC 27711; *telephone:* 919–541–0729; *fax:* 919–541–0237; *e-mail: Murphy.deirdre@epa.gov.* With regard to section IV, contact Mr. Mark Schmidt, Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–04, Research Triangle Park, NC 27711; *telephone:* 919–541–2416; *fax:* 919–541–1903; *e-mail: Schmidt.mark@epa.gov.* With regard to section V, contact Mr. Kevin Cavender, Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–06, Research Triangle Park, NC 27711; *telephone:* 919–541–2364; *fax:* 919–541–1903; *e-mail: Cavender.kevin@epa.gov.* With regard to section VI, contact Mr. Larry Wallace, Ph.D., Air Quality Policy Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C539–01, Research Triangle Park, NC 27711; *telephone:* 919–541–0906; *fax:* 919–541–0824; *e-mail: Wallace.larry@epa.gov.* With regard to section VII, contact Mr. Tom Link, Air Quality Policy Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C539–04, Research Triangle Park, NC 27711; *telephone:* 919–541–5456; *e-mail: Link.tom@epa.gov.*

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I. Summary and Background

A. Summary of Revisions to the Lead NAAQS

Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA is making revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. With regard to the primary standard, EPA is revising various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects. EPA is revising the level to 0.15 μg/m³. EPA is retaining the current indicator of Pb in total suspended particles (Pb-TSP). EPA is revising the averaging time to a rolling 3-month period with a maximum (not-to-be-exceeded) form, evaluated over a 3-year period.

EPA is revising the secondary standard to be identical in all respects to the revised primary standard.

EPA is also revising data handling procedures, including allowance for the use of Pb-PM_{10} data in certain circumstances, and the treatment of exceptional events, and ambient air monitoring and reporting requirements for Pb, including those related to sampling and analysis methods, network design, sampling schedule, and data reporting.

B. Legislative Requirements

Two sections of the Clean Air Act (Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list each air pollutant, emissions of which ''in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health and welfare'' and whose ''presence * * * in the ambient air results from numerous or diverse mobile or stationary sources'' and to issue air quality criteria for those that are listed. Air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [the] pollutant in ambient air * * *''. Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants listed under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

maintenance of which, in the judgment of the Administrator, based on criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied,* 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied,* 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollutant levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Association* v. *EPA,* 647 F.2d at 1156 n. 51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62. In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties that must be addressed. In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 473. Further the Supreme Court ruled that ''[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process * * *'' *Id.* at 472.[3]

Section 109(d)(1) of the Act requires that ''[n]ot later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 and subsection (b) of this section.'' Section 109(d)(2)(A) requires that ''The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.'' Section 109(d)(2)(B) requires that, ''[n]ot later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.'' Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Review of Air Quality Criteria and Standards for Lead

On October 5, 1978, EPA promulgated primary and secondary NAAQS for Pb under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of 1.5 micrograms per cubic meter (μg/m^3), measured as Pb in total suspended particulate matter (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 *Air Quality Criteria for Lead* (USEPA, 1977).

A review of the Pb standards was initiated in the mid-1980s. The scientific assessment for that review is described in the 1986 *Air Quality Criteria for Lead* (USEPA, 1986a), the associated Addendum (USEPA, 1986b) and the 1990 Supplement (USEPA, 1990a). As part of the review, the Agency designed and performed human exposure and health risk analyses (USEPA, 1989), the results of which were presented in a 1990 Staff Paper (USEPA, 1990b). Based on the scientific assessment and the human exposure and health risk analyses, the 1990 Staff Paper presented options for the Pb NAAQS level in the range of 0.5 to 1.5 μg/m^3, and suggested the second highest monthly average in three years for the form and averaging time of the standard (USEPA, 1990b). After consideration of the documents developed during the review and the significantly changed circumstances since Pb was listed in 1976, the Agency did not propose any revisions to the 1978 Pb NAAQS. In a parallel effort, the Agency developed the broad, multi-program, multimedia, integrated *U.S. Strategy for Reducing Lead Exposure* (USEPA, 1991). As part of implementing this strategy, the Agency focused efforts primarily on regulatory and remedial clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose more extensive public health risks to U.S. populations, as well as on actions to reduce Pb emissions to air, such as bringing more areas into compliance with the existing Pb NAAQS (USEPA, 1991).

EPA initiated the current review of the air quality criteria for Pb on November 9, 2004 with a general call for information (69 FR 64926). A project work plan (USEPA, 2005a) for the preparation of the Criteria Document was released in January 2005 for CASAC and public review. EPA held a series of workshops in August 2005, inviting recognized scientific experts to discuss initial draft materials that dealt with various lead-related issues being addressed in the Pb air quality criteria document. In February 2006, EPA released the *Plan for Review of the National Ambient Air Quality Standards for Lead* (USEPA 2006c) that described Agency plans and a timeline for reviewing the air quality criteria, developing human exposure and risk

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] In considering whether the CAA allowed for economic considerations to play a role in the promulgation of the NAAQS, the Supreme Court rejected arguments that because many more factors than air pollution might affect public health, EPA should consider compliance costs that produce health losses in setting the NAAQS. *Whitman* v. *American Trucking Associations,* 531 U.S. at 466. Thus, EPA may not take into account possible public health impacts from the economic cost of implementation. *Id.*

assessments and an ecological risk assessment, preparing a policy assessment, and developing the proposed and final rulemakings.

The first draft of the Criteria Document (USEPA, 2005b) was released for CASAC and public review in December 2005 and discussed at a CASAC meeting held on February 28–March 1, 2006. A second draft Criteria Document (USEPA, 2006b) was released for CASAC and public review in May 2006, and discussed at the CASAC meeting on June 28, 2006. A subsequent draft of *Chapter 7—Integrative Synthesis* (chapter 8 in the final Criteria Document), released on July 31, 2006, was discussed at an August 15, 2006 CASAC teleconference. The final Criteria Document was released on September 30, 2006 (USEPA, 2006a; cited throughout this preamble as CD). While the Criteria Document focuses on new scientific information available since the last review, it integrates that information with scientific information from previous reviews.

In May 2006, EPA released for CASAC and public review a draft *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (USEPA, 2006d), which was discussed at a June 29, 2006 CASAC meeting (Henderson, 2006). The May 2006 assessment plan discussed two assessment phases: A pilot phase and a full-scale phase. The pilot phase of both the human health and ecological risk assessments was presented in the draft *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas* (ICF, 2006; henceforth referred to as the first draft Risk Assessment Report) which was released for CASAC and public review in December 2006. The first draft Staff Paper, also released in December 2006, discussed the pilot assessments and the most policy-relevant science from the Criteria Document. These documents were reviewed by CASAC and the public at a public meeting on February 6–7, 2007 (Henderson, 2007a).

Subsequent to that meeting, EPA conducted full-scale human exposure and health risk assessments, although no further work was done on the ecological assessment due to resource limitations. A second draft Risk Assessment Report (USEPA, 2007a), containing the full-scale human exposure and health risk assessments, was released in July 2007 for review by CASAC at a meeting held on August 28–29, 2007. Taking into consideration CASAC comments (Henderson, 2007b) and public comments on that document, we conducted additional human exposure and health risk assessments. A final Risk Assessment Report (USEPA, 2007b) and final Staff Paper (USEPA, 2007c) were released on November 1, 2007.

The final Staff Paper presents OAQPS staff's evaluation of the public health and welfare policy implications of the key studies and scientific information contained in the Criteria Document and presents and interprets results from the quantitative risk/exposure analyses conducted for this review. Further, the Staff Paper presents OAQPS staff recommendations on a range of policy options for the Administrator to consider concerning whether, and if so how, to revise the primary and secondary Pb NAAQS. Such an evaluation of policy implications is intended to help ''bridge the gap'' between the scientific assessment contained in the Criteria Document and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS for Pb. In evaluating the adequacy of the current standard and a range of alternatives, the Staff Paper considered the available scientific evidence and quantitative risk-based analyses, together with related limitations and uncertainties, and focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: Indicator,[4] averaging time, form,[5] and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the public health and welfare protection afforded by the Pb standards. The information, conclusions, and OAQPS staff recommendations presented in the Staff Paper were informed by comments and advice received from CASAC in its reviews of the earlier draft Staff Paper and drafts of related risk/exposure assessment reports, as well as comments on these earlier draft documents submitted by public commenters.

Subsequent to completion of the Staff Paper, EPA issued an advance notice of proposed rulemaking (ANPR) that was signed by the Administrator on December 5, 2007 (72 FR 71488). The ANPR is one of the key features of the new NAAQS review process that EPA has instituted over the past two years to help to improve the efficiency of the process the Agency uses in reviewing the NAAQS while ensuring that the Agency's decisions are informed by the best available science and broad participation among experts in the scientific community and the public. The ANPR provided the public an opportunity to comment on a wide range of policy options that could be considered by the Administrator.

A public meeting of CASAC was held on December 12–13, 2007 to provide advice and recommendations to the Administrator based on its review of the ANPR and the previously released final Staff Paper and Risk Assessment Report. Transcripts of the meeting and CASAC's letter to the Administrator (Henderson, 2008a) are in the docket for this review and CASAC's letter is also available on the EPA Web site (*http://www.epa.gov/sab*).

A public comment period for the ANPR extended through January 16, 2008 and comments received are in the docket for this review. Comments were received from nearly 9000 private citizens (roughly 200 of them were not part of one of several mass comment campaigns), 13 State and local agencies, one federal agency, three regional or national associations of government agencies or officials, 15 nongovernmental environmental or public health organizations (including one submission on behalf of a coalition of 23 organizations) and five businesses or industry organizations.

The proposed decision (henceforth ''proposal'') on revisions to the Pb NAAQS was signed on May 1, 2008 and published in the **Federal Register** on May 20, 2008. Public teleconferences of the CASAC Pb Panel were held on June 9 and July 8, 2008 to provide advice and recommendations to the Administrator based on its review of the proposal notice. CASAC's letter to the Administrator (Henderson, 2008b) is in the docket for this review and also available on the EPA Web site (*http://www.epa.gov/sab*).

The EPA held two public hearings to provide direct opportunities for oral testimony by the public on the proposal. The hearings were held concurrently on June 12, 2008 in Baltimore, Maryland and St. Louis, Missouri. At these public hearings, EPA heard testimony from 33 individuals representing themselves or specific interested organizations. Transcripts from these hearings and written testimony provided at the hearings are in the docket for this review. Additionally, a large number of written comments were received from various commenters during the public comment period on the proposal. Comments were received from EPA's

[4] The ''indicator'' of a standard defines the chemical species or mixture that is to be measured in determining whether an area attains the standard.

[5] The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

Children's Health Protection Advisory Committee, the American Academy of Pediatrics, the American Medical Association, the American Thoracic Society, two organizations of state and local air agencies (National Association of Clean Air Agencies and Northeast States for Coordinated Air Use Management), approximately 40 State, Tribal and local government agencies, approximately 20 environmental or public health organizations or coalitions, approximately 20 industry organizations or companies, and approximately 6200 private citizens (roughly 150 of whom were not part of one of several mass comment campaigns). Significant issues raised in the public comments are discussed throughout the preamble of this final action. A summary of all other significant comments, along with EPA's responses (henceforth ''Response to Comments''), can be found in the docket for this review.

The schedule for completion of this review has been governed by a judicial order in *Missouri Coalition for the Environment* v. *EPA* (No. 4:04CV00660 ERW, Sept. 14, 2005). The court-ordered schedule governing this review, entered by the court on September 14, 2005 and amended on April 29, 2008 and July 1, 2008, requires EPA to sign, for publication, a notice of final rulemaking concerning its review of the Pb NAAQS no later than October 15, 2008.

Some commenters have referred to and discussed individual scientific studies on the health effects of Pb that were not included in the Criteria Document (EPA, 2006a) (''`new' studies''). In considering and responding to comments for which such ''new'' studies were cited in support, EPA has provisionally considered the cited studies in conjunction with other relevant ''new'' studies published since the completion of the Criteria Document in the context of the findings of the Criteria Document.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the Criteria Document and Staff Paper, which have undergone CASAC and public review. In this Pb NAAQS review, EPA also prepared an ANPR, consistent with the Agency's new NAAQS process. The ANPR discussed studies that were included in the Criteria Document and Staff Paper. The studies assessed in the Criteria Document and Staff Paper, and the integration of the scientific evidence presented in them, have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. EPA's provisional consideration of these studies did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. *See* 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone, ''new'' studies may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, EPA's provisional consideration of ''new'' studies concludes that, taken in context, the ''new'' information and findings do not materially change any of the broad scientific conclusions regarding the health effects and exposure pathways of ambient air Pb made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the Pb air quality criteria that have undergone CASAC and public review. EPA will consider the ''new'' studies for purposes of decision-making in the next periodic review of the Pb NAAQS, which EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these ''new'' studies can be found in the Response to Comments document.

D. Current Related Lead Control Programs

States are primarily responsible for ensuring attainment and maintenance of national ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 of the Act (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 of the Act (42 U.S.C. 7412).

As Pb is a multimedia pollutant, a broad range of Federal programs beyond those that focus on air pollution control provide for nationwide reductions in environmental releases and human exposures. In addition, the Centers for Disease Control and Prevention (CDC) programs provide for the tracking of children's blood Pb levels nationally and provide guidance on levels at which medical and environmental case management activities should be implemented (CDC, 2005a; ACCLPP, 2007).[6] In 1991, the Secretary of the Health and Human Services (HHS) characterized Pb poisoning as the ''number one environmental threat to the health of children in the United States'' (Alliance to End Childhood Lead Poisoning, 1991). In 1997, President Clinton created, by Executive Order 13045, the President's Task Force on Environmental Health Risks and Safety Risks to Children in response to

[6] As described in section II.A.2.a below the CDC stated in 2005 that no ''safe'' threshold for blood Pb levels in young children has been identified (CDC, 2005a).

increased awareness that children face disproportionate risks from environmental health and safety hazards (62 FR 19885).[7] By Executive Orders issued in October 2001 and April 2003, President Bush extended the work for the Task Force for an additional three and a half years beyond its original charter (66 FR 52013 and 68 FR 19931). The Task Force set a Federal goal of eliminating childhood Pb poisoning by the year 2010 and reducing Pb poisoning in children was identified as the Task Force's top priority.

Federal abatement programs provide for the reduction in human exposures and environmental releases from in-place materials containing Pb (*e.g.*, Pb-based paint, urban soil and dust, and contaminated waste sites). Federal regulations on disposal of Pb-based paint waste help facilitate the removal of Pb-based paint from residences (68 FR 36487). Further, in 1991, EPA lowered the maximum levels of Pb permitted in public water systems from 50 parts per billion (ppb) to 15 ppb measured at the consumer's tap (56 FR 26460).

Federal programs to reduce exposure to Pb in paint, dust, and soil are specified under the comprehensive federal regulatory framework developed under the Residential Lead-Based Paint Hazard Reduction Act (Title X). Under Title X and Title IV of the Toxic Substances Control Act (TSCA), EPA has established regulations and associated programs in the following five categories: (1) Training and certification requirements for persons engaged in lead-based paint activities; accreditation of training providers; authorization of State and Tribal lead-based paint programs; and work practice standards for the safe, reliable, and effective identification and elimination of lead-based paint hazards; (2) ensuring that, for most housing constructed before 1978, lead-based paint information flows from sellers to purchasers, from landlords to tenants, and from renovators to owners and occupants; (3) establishing standards for identifying dangerous levels of Pb in paint, dust and soil; (4) providing grant funding to establish and maintain State and Tribal lead-based paint programs, and to address childhood lead poisoning in the highest-risk communities; and (5) providing information on Pb hazards to the public, including steps that people can take to protect themselves and their families from lead-based paint hazards.

Under Title IV of TSCA, EPA established standards identifying hazardous levels of lead in residential paint, dust, and soil in 2001. This regulation supports the implementation of other regulations which deal with worker training and certification, Pb hazard disclosure in real estate transactions, Pb hazard evaluation and control in Federally-owned housing prior to sale and housing receiving Federal assistance, and U.S. Department of Housing and Urban Development grants to local jurisdictions to perform Pb hazard control. The TSCA Title IV term ''lead-based paint hazard'' implemented through this regulation identifies lead-based paint and all residential lead-containing dust and soil regardless of the source of Pb, which, due to their condition and location, would result in adverse human health effects. One of the underlying principles of Title X is to move the focus of public and private decision makers away from the mere presence of lead-based paint, to the presence of lead-based paint hazards, for which more substantive action should be undertaken to control exposures, especially to young children. In addition the success of the program will rely on the voluntary participation of States and Tribes as well as counties and cities to implement the programs and on property owners to follow the standards and EPA's recommendations. If EPA were to set unreasonable standards (*e.g.*, standards that would recommend removal of all Pb from paint, dust, and soil), States and Tribes may choose to opt out of the Title X Pb program and property owners may choose to ignore EPA's advice believing it lacks credibility and practical value. Consequently, EPA needed to develop standards that would not waste resources by chasing risks of negligible importance and that would be accepted by States, Tribes, local governments and property owners. In addition, a separate regulation establishes, among other things, under authority of TSCA section 402, residential Pb dust cleanup levels and amendments to dust and soil sampling requirements (66 FR 1206).

On March 31, 2008, the Agency issued a new rule (Lead: Renovation, Repair and Painting [RRP] Program, 73 FR 21692) to protect children from lead-based paint hazards. This rule applies to renovators and maintenance professionals who perform renovation, repair, or painting in housing, child-care facilities, and schools built prior to 1978. It requires that contractors and maintenance professionals be certified; that their employees be trained; and that they follow protective work practice standards. These standards prohibit certain dangerous practices, such as open flame burning or torching of lead-based paint. The required work practices also include posting warning signs, restricting occupants from work areas, containing work areas to prevent dust and debris from spreading, conducting a thorough cleanup, and verifying that cleanup was effective. The rule will be fully effective by April 2010. The rule contains procedures for the authorization of States, territories, and Tribes to administer and enforce these standards and regulations in lieu of a federal program. In announcing this rule, EPA noted that almost 38 million homes in the United States contain some lead-based paint, and that this rule's requirements were key components of a comprehensive effort to eliminate childhood Pb poisoning. To foster adoption of the rule's measures, EPA also intends to conduct an extensive education and outreach campaign to promote awareness of these new requirements.

Programs associated with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) and Resource Conservation Recovery Act (RCRA) also implement abatement programs, reducing exposures to Pb and other pollutants. For example, EPA determines and implements protective levels for Pb in soil at Superfund sites and RCRA corrective action facilities. Federal programs, including those implementing RCRA, provide for management of hazardous substances in hazardous and municipal solid waste (see, *e.g.*, 66 FR 58258). Federal regulations concerning batteries in municipal solid waste facilitate the collection and recycling or proper disposal of batteries containing Pb.[8] Similarly, Federal programs provide for the reduction in environmental releases of hazardous substances such as Pb in the management of wastewater (*http://www.epa.gov/owm/*).

A variety of federal nonregulatory programs also provide for reduced environmental release of Pb-containing materials through more general encouragement of pollution prevention, promotion of reuse and recycling, reduction of priority and toxic chemicals in products and waste, and

[7] Co-chaired by the Secretary of the HHS and the Administrator of the EPA, the Task Force consisted of representatives from 16 Federal departments and agencies.

[8] *See, e.g.*, ''Implementation of the Mercury-Containing and Rechargeable Battery Management Act'' *http://www.epa.gov/epaoswer/hazwaste/recycle/battery.pdf* and ''Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2005'' *http://www.epa.gov/epaoswer/osw/conserve/resources/msw-2005.pdf.*

conservation of energy and materials. These include the Resource Conservation Challenge (*http://www.epa.gov/epaoswer/osw/conserve/index.htm*), the National Waste Minimization Program (*http://www.epa.gov/epaoswer/hazwaste/minimize/leadtire.htm*), ''Plug in to eCycling'' (a partnership between EPA and consumer electronics manufacturers and retailers; *http://www.epa.gov/epaoswer/hazwaste/recycle/electron/crt.htm#crts*), and activities to reduce the practice of backyard trash burning (*http://www.epa.gov/msw/backyard/pubs.htm*).

As a result of coordinated, intensive efforts at the national, state and local levels, including those programs described above, blood Pb levels in all segments of the population have dropped significantly from levels observed around 1990. In particular, blood Pb levels for the general population of children 1 to 5 years of age have dropped to a median level of 1.6 μg/dL and a level of 3.9 μg/dL for the 90th percentile child in the 2003–2004 National Health and Nutrition Examination Survey (NHANES) as compared to median and 90th percentile levels in 1988–1991 of 3.5 μg/dL and 9.4 μg/dL, respectively (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*). These levels (median and 90th percentile) for the general population of young children [9] are at the low end of the historic range of blood Pb levels for general population of children aged 1–5 years. However, as recognized in section II.A.2.b, levels have been found to vary among children of different socioeconomic status and other demographic characteristics (CD, p. 4–21) and racial/ethnic and income disparities in blood Pb levels in children persist. The Agency has continued to grapple with soil and dust Pb levels from the historical use of Pb in paint and gasoline and from other sources.

In addition to the Pb control programs summarized above, EPA's research program, with other Federal agencies, identifies, encourages and conducts research needed to locate and assess serious risks and to develop methods and tools to characterize and help reduce risks. For example, EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) for Pb in children and the Adult Lead Methodology are widely used and accepted as tools that provide guidance in evaluating site specific data. More recently, in recognition of the need for a single model that predicts Pb concentrations in tissues for children and adults, EPA is developing the All Ages Lead Model (AALM) to provide researchers and risk assessors with a pharmacokinetic model capable of estimating blood, tissue, and bone concentrations of Pb based on estimates of exposure over the lifetime of the individual. EPA research activities on substances including Pb focus on better characterizing aspects of health and environmental effects, exposure, and control or management of environmental releases (see *http://www.epa.gov/ord/researchaccomplishments/index.html*).

E. Summary of Proposed Revisions to the Lead NAAQS

For reasons discussed in the proposal, the Administrator proposed to revise the current primary and secondary Pb standards. With regard to the primary Pb standard, the Administrator proposed to revise the level of the Pb standard to a level within the range of 0.10 μg/m^3 to 0.30 μg/m^3, in conjunction with retaining the current indicator of Pb in total suspended particles (Pb-TSP) but with allowance for the use of Pb-PM_{10} data. With regard to the averaging time and form, the Administrator proposed two options: to retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, revised to apply across a 3-year span; and to revise the averaging time to a calendar month and the form to the second-highest monthly average across a 3-year span. With regard to the secondary standard for Pb, the Administrator proposed to revise the standard to make it identical to the proposed primary standard.

F. Organization and Approach to Final Lead NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current primary and secondary Pb standards. Revisions to the primary standard for Pb are addressed below in section II. The secondary Pb standard is addressed below in section III. Related data completeness, data handling, data reporting and rounding conventions are addressed in section IV, and related ambient monitoring methods and network design are addressed below in section V. Implementation of the revised NAAQS is discussed in section VI, and the exceptional events information submission schedule is described in section VII. A discussion of statutory and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the Criteria Document of scientific information on known and potential human health and welfare effects associated with exposure to Pb in the environment. These final decisions also take into account: (1) Assessments in the Staff Paper and ANPR of the most policy-relevant information in the Criteria Document as well as quantitative exposure and risk assessments based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator, its discussions of drafts of the Criteria Document and Staff Paper, and of the ANPR and the notice of proposed rulemaking at public meetings; (3) public comments received during the development of these documents, either in connection with CASAC Panel meetings or separately; and (4) public comments received on the proposed rulemaking.

II. Rationale for Final Decision on the Primary Standard

A. Introduction

This section presents the rationale for the Administrator's final decision that the current primary standard is not requisite to protect public health with an adequate margin of safety, and that the existing Pb primary standard should be revised. In developing this rationale, EPA has drawn upon an integrative synthesis in the Criteria Document of the entire body of evidence published through late 2006 on human health effects associated with Pb exposure. Some 6000 studies were considered in this review. This body of evidence addresses a broad range of health endpoints associated with exposure to Pb (EPA, 2006a, chapter 8), and includes hundreds of epidemiologic studies conducted in the U.S., Canada, and many countries around the world since the time of the last review (EPA, 2006a, chapter 6).

As discussed below, a significant amount of new research has been conducted since the last review, with important new information coming from epidemiological, toxicological, controlled human exposure, and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review, with extended opportunities for review and comment by the CASAC Panel and the public. As with virtually any policy-relevant scientific research, there is uncertainty

[9] The 5th percentile, geometric mean, and 95th percentile values for the 2003–2004 NHANES are 0.7, 1.8 and 5.1 μg/dL, respectively (Axelrad, 2008a,b).

in the characterization of health effects attributable to exposure to ambient Pb. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient Pb and health effects.

The health effects information and quantitative exposure and health risk assessment were summarized in sections II.B and II.C of the proposal (73 FR at 29193–29220) and are only briefly outlined below in sections II.A.2 and II.A.3. Responses to public comments specific to the material presented in sections II.A.1 through II.A.3 below are provided in the Response to Comments document.

Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that the current standard is not requisite to protect public health with an adequate margin of safety and that it is appropriate to revise the current primary Pb standard to provide additional public health protection (section II.B), as well as a more complete discussion of the Administrator's rationale for retaining or revising the specific elements of the primary Pb standards (section II.C), namely the indicator (section II.C.1), averaging time and form (section II.C.2), and level (section II.C.3). A summary of the final decisions on revisions to the primary Pb standards is presented in section II.D.

1. Overview of Multimedia, Multipathway Considerations and Background

This section briefly summarizes the information presented in section II.A of the proposal and chapter 2 of the Staff Paper on multimedia, multipathway and background considerations of the Pb NAAQS review. As was true in the setting of the current standard, multimedia distribution of and multipathway exposure to Pb that has been emitted into the ambient air play a key role in the Agency's consideration of the Pb NAAQS. Some key multimedia and multipathway considerations in the review include:

(1) Lead is emitted into the air from many sources encompassing a wide variety of stationary and mobile source types. Lead emitted to the air is predominantly in particulate form, with the particles occurring in various sizes. Once emitted, the particles can be transported long or short distances depending on their size, which influences the amount of time spent in aerosol phase. In general, larger particles tend to deposit more quickly, within shorter distances from emissions points, while smaller particles will remain in aerosol phase and travel longer distances before depositing. As summarized in sections II.A.1 and II.E.1 of the proposal, airborne concentrations of Pb at sites near sources are much higher, and the representation of larger particles is greater, than at sites not known to be directly influenced by sources.

(2) Once deposited out of the air, Pb can subsequently be resuspended into the ambient air and, because of the persistence of Pb, Pb emissions contribute to media concentrations for some years into the future.

(3) Exposure to Pb emitted into the ambient air (air-related Pb) can occur directly by inhalation, or indirectly by ingestion of Pb-contaminated food, water or other materials including dust and soil.[10] This occurs as Pb emitted into the ambient air is distributed to other environmental media and can contribute to human exposures via indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation of air. These exposure pathways are described more fully in the proposal.

(4) Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and changes in atmospheric deposition of Pb. Further, because of its persistence in the environment, Pb deposited from the air may contribute to human and ecological exposures for years into the future. Thus, because of the roles of both air concentration and air deposition in human exposure pathways, and because of the persistence of Pb once deposited, some pathways respond more quickly to changes in air quality than others. Pathways most directly involving Pb in ambient air and exchanges of ambient air with indoor air respond more quickly while pathways involving exposure to Pb deposited from ambient air into the environment generally respond more slowly.

Additionally, as when the standard was set, human exposures to Pb include nonair or background contributions in addition to air-related pathways. Some key aspects of the consideration of air and nonair pathways in the review (described in more detail in the proposal) are summarized here:

(1) Human exposure pathways that are not air-related are those in which Pb does not pass through ambient air. These pathways as well as air-related human exposure pathways that involve natural sources of Pb to air are considered ''policy-relevant background'' in this review.

(2) The pathways of human exposure to Pb that are not air-related include ingestion of indoor Pb paint,[11] Pb in diet as a result of inadvertent additions during food processing, and Pb in drinking water attributable to Pb in distribution systems, as well as other generally less prevalent pathways, as described in the proposal (73 FR 29192) and Criteria Document (CD, pp. 3–50 to 3–51).

(3) Some amount of Pb in the air derives from background sources, such as volcanoes, sea salt, and windborne soil particles from areas free of anthropogenic activity and may also derive from anthropogenic sources of airborne Pb located outside of North America (which would also be considered policy-relevant background). In considering contributions from policy-relevant background to human exposures and associated health effects, however, policy-relevant background in air is likely insignificant in comparison to the contributions from exposures to nonair media.

(4) The relative contribution of Pb from different exposure media to human exposure varies, particularly for different age groups. For example, some studies have found that dietary intake of Pb may be a predominant source of Pb exposure among adults, greater than consumption of water and beverages or inhalation, while for young children, ingestion of indoor dust can be a significant Pb exposure pathway (e.g., via hand-to-mouth activity of very young children).

(5) Estimating separate contributions to human Pb exposure from air and nonair sources is complicated by the existence of multiple and varied air-related pathways, as well as the persistent nature of Pb. For example, Pb that is a soil or dust contaminant today may have been airborne yesterday or many years ago. The studies currently available and reviewed in the Criteria Document that evaluate the multiple pathways of Pb exposure, when considering exposure contributions from indoor dust or outdoor dust/soil,

[10] In general, air-related pathways include those pathways where Pb passes through ambient air on its path from a source to human exposure.

[11] Weathering of outdoor Pb paint may also contribute to soil Pb levels adjacent to the house.

do not usually distinguish between air-related and other sources of Pb or between air-related Pb associated with historical emissions and that from recent emissions.[12]

(6) Relative contributions to a child's total Pb exposure from air-related exposure pathways compared to other (nonair-related) Pb exposures depends on many factors including ambient air concentrations and air deposition in the area where the child resides (as well as in the area from which the child's food derives) and access to other sources of Pb exposure such as Pb paint, tap water affected by plumbing containing Pb, and lead-tainted products. Studies indicate that in the absence of paint-related exposures, Pb from other sources such as stationary sources of Pb emissions may dominate a child's Pb exposures. In other cases, such as children living in older housing with peeling paint or where renovations have occurred, the dominant source of Pb exposure may be lead paint used in the house in the past. Depending on Pb levels in a home's tap water, drinking water can sometimes be a significant source. In still other cases, there may be more of a mixture of contributions from multiple sources, with no one source dominating.

2. Overview of Health Effects Information

This section summarizes information presented in section II.B of the proposal pertaining to health endpoints associated with the range of exposures considered to be most relevant to current exposure levels. In recognition of the role of multiple exposure pathways and routes and the use of an internal exposure or dose metric in evaluating health risk for Pb, the following section summarizes key aspects of the internal disposition or distribution of Pb, the use of blood Pb as an internal exposure or dose metric, and the evidence with regard to the quantitative relationship between air Pb and blood Pb levels (section II.A.2.a). This is followed first by a summary of the broad array of Pb-induced health effects and recognition of at-risk subpopulations (section II.A.2.b) and then by a summary of neurological effects in children and quantitative concentration-response relationships for blood Pb and IQ (section II.A.2.c).

a. Blood Lead

(i) Internal Disposition of Lead

Lead enters the body via the respiratory system and gastrointestinal tract, from which it is quickly absorbed into the blood stream and distributed throughout the body.[13] Lead bioaccumulates in the body, with the bone serving as a large, long-term storage compartment; soft tissues (e.g., kidney, liver, brain, etc.) serve as smaller compartments, in which Pb may be more mobile (CD, sections 4.3.1.4 and 8.3.1). During childhood development, bone represents approximately 70% of a child's body burden of Pb, and this accumulation continues through adulthood, when more than 90% of the total Pb body burden is stored in the bone (CD, section 4.2.2). Throughout life, Pb in the body is exchanged between blood and bone, and between blood and soft tissues (CD, section 4.3.2), with variation in these exchanges reflecting ''duration and intensity of the exposure, age and various physiological variables'' (CD, p. 4–1).

The bone pool of Pb in children is thought to be much more labile than that in adults due to the more rapid turnover of bone mineral as a result of growth (CD, p. 4–27). As a result, changes in blood Pb concentration in children more closely parallel changes in total body burden (CD, pp. 4–20 and 4–27). This is in contrast to adults, whose bone has accumulated decades of Pb exposures (with past exposures often greater than current ones), and for whom the bone may be a significant source long after exposure has ended (CD, section 4.3.2.5).

(ii) Use of Blood Pb as Dose Metric

Blood Pb levels are extensively used as an index or biomarker of exposure by national and international health agencies, as well as in epidemiological (CD, sections 4.3.1.3 and 8.3.2) and toxicological studies of Pb health effects and dose-response relationships (CD, chapter 5). The U.S. Centers for Disease Control and Prevention (CDC), and its predecessor agencies, have for many years used blood Pb level as a metric for identifying children at risk of adverse health effects and for specifying particular public health recommendations (CDC, 1991; CDC, 2005a). Most recently, in 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 μg/dL[14] and the data demonstrating that no ''safe'' threshold for blood Pb had been identified, and emphasizing the importance of preventative measures (CDC, 2005a, ACCLPP, 2007).[15]

Since 1976, the CDC has been monitoring blood Pb levels in multiple age groups nationally through the National Health and Nutrition Examination Survey (NHANES).[16] The NHANES information has documented the dramatic decline in mean blood Pb levels in the U.S. population that has occurred since the 1970s and that coincides with regulations regarding leaded fuels, leaded paint, and Pb-containing plumbing materials that have reduced Pb exposure among the general population (CD, sections 4.3.1.3 and 8.3.3; Schwemberger *et al.*, 2005). The

[12] The exposure assessment for children performed for this review employed available data and methods to develop estimates intended to inform a characterization of these pathways (as described in the proposal and the final Risk Assessment Report).

[13] Additionally, Pb freely crosses the placenta resulting in continued fetal exposure throughout pregnancy, with that exposure increasing during the latter half of pregnancy (CD, section 6.6.2).

[14] As described by the Advisory Committee on Childhood Lead Poisoning Prevention, ''In 1991, CDC defined the blood lead level (BLL) that should prompt public health actions as 10 μg/dL. Concurrently, CDC also recognized that a BLL of 10 μg/dL did not define a threshold for the harmful effects of lead. Research conducted since 1991 has strengthened the evidence that children's physical and mental development can be affected at BLLS <10 μg/dL'' (ACCLPP, 2007).

[15] With the 2005 statement, CDC did not lower the 1991 level of concern and identified a variety of reasons, reflecting both scientific and practical considerations, for not doing so, including a lack of effective clinical or public health interventions to reliably and consistently reduce blood Pb levels that are below 10 μg/dL, the lack of a demonstrated threshold for adverse effects, and concerns for deflecting resources from children with higher blood Pb levels (CDC, 2005a, pp. 2–3). The preface for the CDC statement included the following: ''Although there is evidence of adverse health effects in children with blood lead levels below 10 μg/dL, CDC has not changed its level of concern, which remains at levels >10 μg/dL. We believe it critical to focus available resources where the potential adverse effects remain the greatest. If no threshold level exists for adverse health effects, setting a new BLL of concern somewhere below 10 μg/dL would be based on an arbitrary decision. In addition, the feasibility and effectiveness of individual interventions to further reduce BLLs below 10 μg/dL has not been demonstrated.'' [CDC, 2005a, p. ix] CDC further stated ''Nonetheless, the sources of lead exposure and the population-based interventions that can be expected to reduce lead exposure are similar in children with BLLs <10 μg/ dL and >10 μg/dL, so preventive lead hazard control measures need not be deferred pending further research findings or consensus.'' [CDC, 2005a, p. 2] CDC's Advisory Committee on Childhood Lead Poisoning Prevention recently provided recommendations regarding interpreting and managing blood Pb levels below 10 μg/dL in children and reducing childhood exposures to Pb (ACCLPP, 2007).

[16] This information documents a variation in mean blood Pb levels across the various age groups monitored. For example, mean blood Pb levels in 2001–2002 for ages 1–5, 6–11, 12–19 and greater than or equal to 20 years of age, are 1.70, 1.25, 0.94, and 1.56 μg/dL, respectively (CD, p. 4–22).

Criteria Document summarizes related information as follows (CD, p. E–6).

In the United States, decreases in mobile sources of Pb, resulting from the phasedown of Pb additives created a 98% decline in emissions from 1970 to 2003. NHANES data show a consequent parallel decline in blood-Pb levels in children aged 1 to 5 years from a geometric mean of ~15 μg/dL in 1976–1980 to ~1–2 μg/dL in the 2000–2004 period.

While blood Pb levels in the U.S. general population, including geometric mean levels in children aged 1–5, have declined significantly, levels have been found to vary among children of different socioeconomic status (SES) and other demographic characteristics (CD, p. 4–21), and racial/ethnic and income disparities in blood Pb levels in children persist. For example, as described in the proposal, blood Pb levels for lower income and African American children are higher than those for the general population. The recently released RRP rule (discussed above in section I.C) is expected to contribute to further reductions in blood Pb levels for children living in houses with Pb paint.

(iii) Air-to-Blood Relationships

As described in section II.A.1 above and discussed in section II.A of the proposal, Pb in ambient air contributes to Pb in blood by multiple pathways, with the pertinent exposure routes including both inhalation and ingestion (CD, sections 3.1.3.2, 4.2 and 4.4; Hilts, 2003). The quantitative relationship between ambient air Pb and blood Pb (discussed in section II.B.1.c of the proposal), which is often termed a slope or ratio, describes the increase in blood Pb (in μg/dL) estimated to be associated with each unit increase of air Pb (in μg/m^3).[17]

The evidence on this quantitative relationship is now, as in the past, limited by the circumstances in which the data are collected. These estimates are generally developed from studies of populations in various Pb exposure circumstances. The 1986 Criteria Document discussed the studies available at that time that addressed the relationship between air Pb and blood Pb,[18] recognizing that there is significant variability in air-to-blood ratios for different populations exposed to Pb through different air-related exposure pathways and at different exposure levels.

In discussing the available evidence, the 1986 Criteria Document observed that estimates of air-to-blood ratios that included air-related ingestion pathways in addition to the inhalation pathway are ''necessarily higher'', in terms of blood Pb response, than those estimates based on inhalation alone (USEPA 1986a, p. 11–106). Thus, the extent to which studies account for the full set of air-related inhalation and ingestion exposure pathways affects the magnitude of the resultant air-to-blood estimates, such that fewer pathways included as ''air-related'' yields lower ratios. The 1986 Criteria Document also observed that ratios derived from studies focused only on inhalation pathways (e.g., chamber studies, occupational studies) have generally been on the order of 1:2 or lower, while ratios derived from studies including more air-related pathways were generally higher (USEPA, 1986a, p. 11–106). Further, the current evidence appears to indicate higher ratios for children as compared to those for adults (USEPA, 1986a), perhaps due to behavioral differences between the age groups.

Reflecting these considerations, the 1986 Criteria Document identified a range of air-to-blood ratios for children that reflected both inhalation and ingestion-related air Pb contributions as generally ranging from 1:3 to 1:5 based on the information available at that time (USEPA 1986a, p. 11–106). Table 11–36 (p. 11–100) in the 1986 Criteria Document (drawn from Table 1 in Brunekreef, 1984) presents air-to-blood ratios from a number of studies in children (i.e., those with identified air monitoring methods and reliable blood Pb data). For example, air-to-blood ratios from the subset of those studies that used quality control protocols and presented adjusted slopes[19] include adjusted ratios of 3.6 (Zielhuis *et al.*, 1979), 5.2 (Billick *et al.*, 1979, 1980); 2.9 (Billick *et al.*, 1983), and 8.5 (Brunekreef et al., 1983).

Additionally, the 1986 Criteria Document noted that ratios derived from studies involving higher blood and air Pb levels are generally smaller than ratios from studies involving lower blood and air Pb levels (USEPA, 1986a. p. 11–99). In consideration of this factor, the proposal observed that the range of 1:3 to 1:5 in air-to-blood ratios for children noted in the 1986 Criteria Document generally reflected study populations with blood Pb levels in the range of approximately 10–30 μg/dL (USEPA 1986a, pp. 11–100; Brunekreef, 1984), much higher than those common in today's population. This observation suggests that air-to-blood ratios relevant for today's population of children would likely extend higher than the 1:3 to 1:5 range identified in the 1986 Criteria Document.

More recently, a study of changes in children's blood Pb levels associated with reduced Pb emissions and associated air concentrations near a Pb smelter in Canada (for children through age six in age) reports a ratio of 1:6, and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7 (CD, pp. 3–23 to 3–24; Hilts, 2003).[20] Ambient air and blood Pb levels associated with the Hilts (2003) study range from 1.1 to 0.03 μg/m^3, and associated population mean blood Pb levels range from 11.5 to 4.7 μg/dL, which are lower than levels associated with the older studies cited in the 1986 Criteria Document (USEPA, 1986).

[17] Ratios are presented in the form of 1:x, with the 1 representing air Pb (in μg/m^3) and x representing blood Pb (in μg/dL). Description of ratios as higher or lower refers to the values for x (i.e., the change in blood Pb per unit of air Pb). Slopes are presented as simply the value of x.

[18] We note that the 2006 Criteria Document did not include a discussion of more recent studies relating to air-to-blood ratios; more recent studies were discussed in the Staff Paper, including discussion by CASAC in their review of those documents.

[19] Brunekreef *et al.* (1984) discusses potential confounders to the relationship between air Pb and blood Pb, recognizing that ideally all possible confounders should be taken into account in deriving an adjusted air-to-blood relationship from a community study. The studies cited here adjusted for parental education (Zielhuis *et al.*, 1979), age and race (Billick *et al.*, 1979, 1980) and additionally measuring height of air Pb (Billick *et al.*, 1983); Brunekreef *et al.* (1984) used multiple regression to control for several confounders. The authors conclude that ''presentation of both unadjusted and (stepwise) adjusted relationships is advisable, to allow insight in the range of possible values for the relationship'' (p. 83). Unadjusted ratios were presented for two of these studies, including ratios of 4.0 (Zielhuis *et al.*, 1979) and 18.5 (Brunekreef *et al.*, 1983). The proposal noted that the Brunekreef *et al.*, 1983 study is subject to a number of sources of uncertainty that could result in air-to-blood Pb ratios that are biased high, including the potential for underestimating ambient air Pb levels due to the use of low volume British Smoke air monitors and the potential for higher historical ambient air Pb levels to have influenced blood Pb levels (see Section V.B.1 of the 1989 Pb Staff Report for the Pb NAAQS review, EPA, 1989). In addition, the 1989 Staff Report notes that the higher air-to-blood ratios obtained from this study could reflect the relatively lower blood Pb levels seen across the study population (compared with blood Pb levels reported in other studies from that period).

[20] This study considered changes in ambient air Pb levels and associated blood Pb levels over a five-year period which included closure of an older Pb smelter and subsequent opening of a newer facility in 1997 and a temporary (3 month) shutdown of all smelting activity in the summer of 2001. The author observed that the air-to-blood ratio for children in the area over the full period was approximately 1:6. The author noted limitations in the dataset associated with exposures in the second time period, after the temporary shutdown of the facility in 2001, including sampling of a different age group at that time and a shorter time period (3 months) at these lower ambient air Pb levels prior to collection of blood Pb levels. Consequently, EPA calculated an alternate air-to-blood Pb ratio based on consideration for ambient air Pb and blood Pb reductions in the first time period (after opening of the new facility in 1997).

The proposal identified sources of uncertainty related to air-to-blood ratios obtained from Hilts (2003). One such area of uncertainty relates to the pattern of changes in indoor Pb dustfall (presented in Table 3 in the article) which suggests a potentially significant decrease in Pb impacts to indoor dust prior to closure of an older Pb smelter and start-up of a newer facility in 1997. Some have suggested that this earlier reduction in indoor dustfall suggests that a significant portion of the reduction in Pb exposure (and therefore, the blood Pb reduction reflected in air-to-blood ratios) may have resulted from efforts to increase public awareness of the Pb contamination issue (e.g., through increased cleaning to reduce indoor dust levels) rather than reductions in ambient air Pb and associated indoor dust Pb contamination. In addition, notable fluctuations in blood Pb levels observed prior to 1997 (as seen in Figure 2 of the article) have raised questions as to whether factors other than ambient air Pb reduction could be influencing decreases in blood Pb. [21]

In addition to the study by Hilts (2003), we are aware of two other studies published since the 1986 Criteria Document that report air-to-blood ratios for children (Tripathi *et al.*, 2001 and Hayes *et al.*, 1994). These studies were not cited in the 2006 Criteria Document, but were referenced in public comments received by EPA during this review.[22] The study by Tripathi *et al.* (2001) reports an air-to-blood ratio of approximately 1:3.6 for an analysis of children aged six through ten in India. The ambient air and blood Pb levels in this study (geometric mean blood Pb levels generally ranged from 10 to 15 μg/dL) are similar to levels reported in older studies reviewed in the 1986 Criteria Document and are much higher than current conditions in the U.S. The study by Hayes *et al.* (1994) compared patterns of ambient air Pb reductions and blood Pb reductions for large numbers of children in Chicago between 1971 and 1988, a period when significant reductions occurred in both measures. The study reports an air-to-blood ratio of 1:5.6 associated with ambient air Pb levels near 1 μg/m^3 and a ratio of 1:16 for ambient air Pb levels in the range of 0.25 μg/m^3, indicating a pattern of higher ratios with lower ambient air Pb and blood Pb levels consistent with conclusions in the 1986 Criteria Document.[23]

In their advice to the Agency prior to the proposal, CASAC identified air-to-blood ratios of 1:5, as used by the World Health Organization (2000), and 1:10, as supported by an empirical analysis of changes in air Pb and changes in blood Pb between 1976 and the time when the phase-out of Pb from gasoline was completed (Henderson, 2007a).[24]

In the proposal, beyond considering the evidence presented in the published literature and that reviewed in Pb Criteria Documents, we also considered air-to-blood ratios derived from the exposure assessment for this review (summarized below in section II.A.3 and described in detail in USEPA, 2007b). In that assessment, current modeling tools and information on children's activity patterns, behavior and physiology (e.g., CD, section 4.4) were used to estimate blood Pb levels associated with multimedia and multipathway Pb exposure. The results from the various case studies included in this assessment, with consideration of the context in which they were derived (e.g., the extent to which the range of air-related pathways were simulated), are also informative to our understanding of air-to-blood ratios.

For the general urban case study, air-to-blood ratios ranged from 1:2 to 1:9 across the alternative standard levels assessed, which ranged from the current standard of 1.5 μg/m^3 down to a level of 0.02 μg/m^3. This pattern of model-derived ratios generally supports the range of ratios obtained from the literature and also supports the observation that lower ambient air Pb levels are associated with higher air-to-blood ratios. There are a number of sources of uncertainty associated with these model-derived ratios. The hybrid indoor dust Pb model, which is used in estimating indoor dust Pb levels for the urban case studies, uses a U.S. Department of Housing and Urban Development (HUD) survey dataset reflecting housing constructed before 1980 in establishing the relationship between dust loading and concentration, which is a key component in the hybrid dust model (as described in the Risk Assessment Report, Volume II, Appendix G, Attachment G–1). Given this application of the HUD dataset, there is the potential that the nonlinear relationship between indoor dust Pb loading and concentration (which is reflected in the structure of the hybrid dust model) could be driven more by the presence of indoor Pb paint than contributions from outdoor ambient air Pb. We also note that only recent air pathways were adjusted in modeling the impact of ambient air Pb reductions on blood Pb levels in the urban case studies, which could have implications for the air-to-blood ratios.

For the primary Pb smelter (subarea) case study, air-to-blood ratios ranged from 1:10 to 1:19 across the same range of alternative standard levels, from 1.5 down to 0.02 μg/m^3.[25] Because these ratios are based on regression modeling developed using empirical data, there is the potential for these ratios to capture more fully the impact of ambient air on indoor dust Pb, and ultimately blood Pb, including longer timeframe impacts resulting from changes in outdoor deposition. Therefore, given that these ratios are higher than ratios developed for the general urban case study using the hybrid indoor dust Pb model (which only considers reductions in recent air), the ratios estimated for the primary Pb smelter (subarea) support the evidence-based observation discussed above that consideration of more of the exposure pathways relating ambient air Pb to blood Pb, may result in higher air-to-blood Pb ratios. In considering this case study, some have suggested, however, that the regression modeling fails to accurately reflect the temporal relationship between reductions in ambient air Pb and indoor dust Pb, which could result in an over-estimate

[21] In the publication, the author acknowledges that remedial programs (e.g., community and home-based dust control and education) may have been responsible for some of the blood Pb reduction seen during the study period (1997 to 2001). However, the author points out that these programs were in place in 1992 and he suggests that it is unlikely that they contributed to the sudden drop in blood Pb levels occurring after 1997. In addition, the author describes a number of aspects of the analysis which could have implications for air-to-blood ratios including a tendency over time for children with lower blood Pb levels to not return for testing, and inclusion of children aged 6 to 36 months in Pb screening in 2001 (in contrast to the wider age range up to 60 months as was done in previous years).

[22] EPA is not basing its decisions on these two studies, but notes that these estimates are consistent with other studies that were included in the 1986 and 2006 Criteria Documents and considered by CASAC and the public.

[23] As with all studies, we note that there are strengths and limitations for these two studies which may affect the specific magnitudes of the reported ratios, but that the studies' findings and trends are generally consistent with the conclusions from the 1986 Criteria Document.

[24] The CASAC Panel stated ''The Schwartz and Pitcher analysis showed that in 1978, the midpoint of the National Health and Nutrition Examination Survey (NHANES) II, gasoline Pb was responsible for 9.1 μg/dL of blood Pb in children. Their estimate is based on their coefficient of 2.14 μg/dL per 100 metric tons (MT) per day of gasoline use, and usage of 426 MT/day in 1976. Between 1976 and when the phase-out of Pb from gasoline was completed, air Pb concentrations in U.S. cities fell a little less than 1 μg/m^3 (24). These two facts imply a ratio of 9–10 μg/dL per μg/m^3 reduction in air Pb, taking all pathways into account.'' (Henderson, 2007a, pp. D–2 to D–3).

[25] Air-to-blood ratios for the full study area of the primary Pb smelter range from 1:3 to 1:7 across the range of alternative standard levels from 1.5 down to 0.02 μg/m^3 (USEPA, 2007b).

of the degree of dust Pb reduction associated with a specified degree of ambient air Pb reduction, which in turn could produce air-to-blood Pb ratios that are biased high.

In summary, EPA's view in the proposal was that the current evidence in conjunction with the results and observations drawn from the exposure assessment, including related uncertainties, supports consideration of a range of air-to-blood ratios for children ranging from 1:3 to 1:7, reflecting multiple air-related pathways beyond simply inhalation and the lower air and blood Pb levels pertinent to this review. EPA invited comment on this range as well as the appropriate weight to place on specific ratios within this range. Advice from CASAC and comments from the public on this issue are discussed below in section II.C.3.

b. Array of Health Effects and At-Risk Subpopulations

Lead has been demonstrated to exert ''a broad array of deleterious effects on multiple organ systems via widely diverse mechanisms of action'' (CD, p. 8–24 and section 8.4.1). This array of health effects includes effects on heme biosynthesis and related functions; neurological development and function; reproduction and physical development; kidney function; cardiovascular function; and immune function. The weight of evidence varies across this array of effects and is comprehensively described in the Criteria Document. There is also some evidence of Pb carcinogenicity, primarily from animal studies, together with limited human evidence of suggestive associations (CD, sections 5.6.2, 6.7, and 8.4.10).[26]

This review is focused on those effects most pertinent to ambient exposures, which, given the reductions in ambient Pb levels over the past 30 years, are generally those associated with individual blood Pb levels in children and adults in the range of 10 µg/dL and lower. These key effects include neurological, hematological and immune [27] effects for children, and hematological, cardiovascular and renal effects for adults (CD, Tables 8–5 and 8–6, pp. 8–60 to 8–62). As evident from the discussions in chapters 5, 6 and 8 of the Criteria Document, ''neurotoxic effects in children and cardiovascular effects in adults are among those best substantiated as occurring at blood Pb concentrations as low as 5 to 10 µg/dL (or possibly lower); and these categories are currently clearly of greatest public health concern'' (CD, p. 8–60).[28] [29] The toxicological and epidemiological information available since the time of the last review ''includes assessment of new evidence substantiating risks of deleterious effects on certain health endpoints being induced by distinctly lower than previously demonstrated Pb exposures indexed by blood Pb levels extending well below 10 µg/dL in children and/or adults'' (CD, p. 8–25). Some health effects associated with individual blood Pb levels extend below 5 µg/dL, and some studies have observed these effects at the lowest blood levels considered. With regard to population mean levels, the Criteria Document points to studies reporting ''Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 µg/dL'' (CD, p. E–9).

We note that many studies over the past decade, in investigating effects at lower blood Pb levels, have utilized the CDC advisory level or level of concern for individual children (10 µg/dL) [30] as a benchmark for assessment, and this is reflected in the numerous references in the Criteria Document to 10 µg/dL. Individual study conclusions stated with regard to effects observed below 10 µg/dL are usually referring to individual blood Pb levels. In fact, many such study groups have been restricted to individual blood Pb levels below 10 µg/dL or below levels lower than 10 µg/dL. We note that the mean blood Pb level for these groups will necessarily be lower than the blood Pb level they are restricted below.

Threshold levels, in terms of blood Pb levels in individual children, for neurological effects cannot be discerned from the currently available studies (CD, pp. 8–60 to 8–63). The Criteria Document states ''There is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects'' (CD, p. 8–63). As discussed in the Criteria Document, ''a threshold for Pb neurotoxic effects may exist at levels distinctly lower than the lowest exposures examined in these epidemiologic studies'' (CD, p. 8–67).[31]

As described in the proposal, physiological, behavioral and demographic factors contribute to increased risk of Pb-related health effects. Potentially at-risk subpopulations, also referred to as sensitive sub-populations, include those with increased susceptibility (*i.e.*, physiological factors contributing to a greater response for the same exposure), as well as those with greater vulnerability (*i.e.*, those with increased exposure such as through exposure to higher media concentrations or resulting from behavior leading to increased contact with contaminated media), or those affected by socioeconomic factors, such as reduced access to health care or low socioeconomic status.

While adults are susceptible to Pb effects at lower blood Pb levels than previously understood (*e.g.*, CD, p. 8–25), the greater influence of past exposures on their current blood Pb levels (as summarized above in section II.A.2.a) leads us to give greater prominence to children as the sensitive subpopulation in this review. Children are at increased risk of Pb-related health effects due to various factors that enhance their exposures (*e.g.*, via the hand-to-mouth activity that is prevalent in very young children, CD, section 4.4.3) and susceptibility. While children are considered to be at a period of

[26] Lead has been classified as a probable human carcinogen by the International Agency for Research on Cancer (inorganic lead compounds), based mainly on sufficient animal evidence, and as reasonably anticipated to be a human carcinogen by the U.S. National Toxicology Program (lead and lead compounds) (CD, Section 6.7.2). U.S. EPA considers Pb a probable carcinogen (*http://www.epa.gov/iris/subst/0277.htm;* CD, p. 6–195).

[27] At mean blood Pb levels, in children, on the order of 10 µg/dL, and somewhat lower, associations have been found with effects to the immune system, including altered macrophage activation, increased IgE levels and associated increased risk for autoimmunity and asthma (CD, Sections 5.9, 6.8, and 8.4.6).

[28] With regard to blood Pb levels in individual children associated with particular neurological effects, the Criteria Document states ''Collectively, the prospective cohort and cross-sectional studies offer evidence that exposure to Pb affects the intellectual attainment of preschool and school age children at blood Pb levels <10 µg/dL (most clearly in the 5 to 10 µg/dL range, but, less definitively, possibly lower).'' (p. 6–269)

[29] Epidemiological studies have consistently demonstrated associations between Pb exposure and enhanced risk of deleterious cardiovascular outcomes, including increased blood pressure and incidence of hypertension. A meta-analysis of numerous studies estimates that a doubling of blood-Pb level (*e.g.*, from 5 to 10 µg/dL) is associated with ~1.0 mm Hg increase in systolic blood pressure and ~0.6 mm Hg increase in diastolic pressure (CD, p. E–10).

[30] This level has variously been called an advisory level or level of concern (*http://www.atsdr.cdc.gov/csem/lead/pb_standards2.html*). In addressing children's blood Pb levels, CDC has stated ''Specific strategies that target screening to high-risk children are essential to identify children with BLLs ≥ 10 µg/dL.'' (CDC, 2005, p.1)

[31] In consideration of the evidence from experimental animal studies with regard to the issue of threshold for neurotoxic effects, the CD notes that there is little evidence that allows for clear delineation of a threshold, and that ''blood-Pb levels associated with neurobehavioral effects appear to be reasonably parallel between humans and animals at reasonably comparable blood-Pb concentrations; and such effects appear likely to occur in humans ranging down at least to 5–10 µg/dL, or possibly lower (although the possibility of a threshold for such neurotoxic effects cannot be ruled out at lower blood-Pb concentrations)'' (CD, p. 8–38).

maximum exposure around 18–27 months, the current evidence has found even stronger associations between blood Pb at school age and IQ at school age. The evidence ''supports the idea that Pb exposure continues to be toxic to children as they reach school age, and [does] not lend support to the interpretation that all the damage is done by the time the child reaches 2 to 3 years of age'' (CD, section 6.2.12). The following physiological and demographic factors can further affect risk of Pb-related effects in some children.

- Children with particular genetic polymorphisms (*e.g.*, presence of the δ-aminolevulinic acid dehydratase-2 [ALAD-2] allele) have increased sensitivity to Pb toxicity, which may be due to increased susceptibility to the same internal dose and/or to increased internal dose associated with same exposure (CD, p. 8–71, sections 6.3.5, 6.4.7.3 and 6.3.6).
- Some children may have blood Pb levels higher than those otherwise associated with a given Pb exposure (CD, section 8.5.3) as a result of nutritional status (e.g., iron deficiency, calcium intake), as well as genetic and other factors (CD, chapter 4 and sections 3.4, 5.3.7 and 8.5.3).
- Situations of elevated exposure, such as residing near sources of ambient Pb, as well as socioeconomic factors, such as reduced access to health care or low socioeconomic status (SES) (USEPA, 2003, 2005c) can also contribute to increased blood Pb levels and increased risk of associated health effects from air-related Pb.
- As described in the proposal (sections II.B.1.b and II.B.3), children in poverty and black, non-Hispanic children have notably higher blood Pb levels than do economically well-off children and white children, in general.

c. Neurological Effects in Children

Among the wide variety of health endpoints associated with Pb exposures, there is general consensus that the developing nervous system in children is among the, if not the, most sensitive. While blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels (CD, chapter 6). Functional manifestations of Pb neurotoxicity during childhood include sensory, motor, cognitive and behavioral impacts. Numerous epidemiological studies have reported neurocognitive, neurobehavioral, sensory, and motor function effects in children with blood Pb levels below 10 μg/dL (CD, sections 6.2 and 8.4).[32] As discussed in the Criteria Document, ''extensive experimental laboratory animal evidence has been generated that (a) substantiates well the plausibility of the epidemiologic findings observed in human children and adults and (b) expands our understanding of likely mechanisms underlying the neurotoxic effects'' (CD, p. 8–25; section 5.3).

Cognitive effects associated with Pb exposures that have been observed in epidemiological studies have included decrements in intelligence test results, such as the widely used IQ score, and in academic achievement as assessed by various standardized tests as well as by class ranking and graduation rates (CD, section 6.2.16 and pp 8–29 to 8–30). As noted in the Criteria Document with regard to the latter, ''Associations between Pb exposure and academic achievement observed in the above-noted studies were significant even after adjusting for IQ, suggesting that Pb-sensitive neuropsychological processing and learning factors not reflected by global intelligence indices might contribute to reduced performance on academic tasks'' (CD, pp 8–29 to 8–30).

With regard to potential implications of Pb effects on IQ, the Criteria Document recognizes the ''critical'' distinction between population and individual risk, identifying issues regarding declines in IQ for an individual and for the population. The Criteria Document further states that a ''point estimate indicating a modest mean change on a health index at the individual level can have substantial implications at the population level'' (CD, p. 8–77).[33] A downward shift in the mean IQ value is associated with both substantial decreases in percentages achieving very high scores and substantial increases in the percentage of individuals achieving very low scores (CD, p. 8–81).[34] For an individual functioning in the low IQ range due to the influence of developmental risk factors other than Pb, a Pb-associated IQ decline of several points might be sufficient to drop that individual into the range associated with increased risk of educational, vocational, and social failure (CD, p. 8–77).

Other cognitive effects observed in studies of children have included effects on attention, executive functions, language, memory, learning and visuospatial processing (CD, sections 5.3.5, 6.2.5 and 8.4.2.1), with attention and executive function effects associated with Pb exposures indexed by blood Pb levels below 10 μg/dL (CD, section 6.2.5 and pp. 8–30 to 8–31). The evidence for the role of Pb in this suite of effects includes experimental animal findings (discussed in CD, section 8.4.2.1; p. 8–31), which provide strong biological plausibility of Pb effects on learning ability, memory and attention (CD, section 5.3.5), as well as associated mechanistic findings.

The persistence of such Pb-induced effects is described in the proposal and the Criteria Document (e.g., CD, sections 5.3.5, 6.2.11, and 8.5.2). The persistence or irreversibility of such effects can be the result of damage occurring without adequate repair offsets or of the persistence of Pb in the body (CD, section 8.5.2). It is additionally important to note that there may be long-term consequences of such deficits over a lifetime. Poor academic skills and achievement can have ''enduring and important effects on objective parameters of success in real life'', as well as increased risk of antisocial and delinquent behavior (CD, section 6.2.16).

Multiple epidemiologic studies of Pb and child development have demonstrated inverse associations between blood Pb concentrations and children's IQ and other cognitive-related outcomes at successively lower Pb exposure levels over the past 30 years (as discussed in the CD, section 6.2.13). For example, the overall weight of the available evidence, described in the Criteria Document, provides clear substantiation of neurocognitive decrements being associated in children with mean blood Pb levels in the range of 5 to 10 μg/dL, and some analyses indicate Pb effects on intellectual attainment of children for which population mean blood Pb levels in the analysis ranged from 2 to 8 μg/dL (CD, sections 6.2, 8.4.2 and 8.4.2.6). Thus, while blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with blood Pb levels similar to the more recent, lower blood Pb levels (CD,

[32] Further, neurological effects in general include behavioral effects, such as delinquent behavior (CD, sections 6.2.6 and 8.4.2.2), sensory effects, such as those related to hearing and vision (CD, sections 6.2.7 and 8.4.2.3), and deficits in neuromotor function (CD, p. 8–36).

[33] As an example, the Criteria Document states ''although an increase of a few mmHg in blood pressure might not be of concern for an individual's well-being, the same increase in the population mean might be associated with substantial increases in the percentages of individuals with values that are sufficiently extreme that they exceed the criteria used to diagnose hypertension'' (CD, p. 8–77).

[34] For example, for a population mean IQ of 100 (and standard deviation of 15), 2.3% of the population would score above 130, but a shift of the population to a mean of 95 results in only 0.99% of the population scoring above 130 (CD, pp. 8–81 to 8–82).

chapter 6; and as discussed in section II.B.2.b of the proposal).

The current evidence reviewed in the Criteria Document with regard to the quantitative relationship between neurocognitive decrement, such as IQ, and blood Pb levels indicates that the slope for Pb effects on IQ is nonlinear and is steeper at lower blood Pb levels, such that each µg/dL increase in blood Pb may have a greater effect on IQ at lower blood Pb levels (*e.g.,* below 10 µg/dL) than at higher levels (CD, section 6.2.13; pp. 8–63 to 8–64; Figure 8–7). As stated in the CD, ''the most compelling evidence for effects at blood Pb levels <10 µg/dL, as well as a nonlinear relationship between blood Pb levels and IQ, comes from the international pooled analysis of seven prospective cohort studies (n=1,333) by Lanphear et al. (2005)'' (CD, pp. 6–67 and 8–37 and section 6.2.3.1.11). Using the full pooled dataset with concurrent blood Pb level as the exposure metric and IQ as the response from the pooled dataset of seven international studies, Lanphear and others (2005) employed mathematical models of various forms, including linear, cubic spline, log-linear, and piece-wise linear, in their investigation of the blood Pb concentration-response relationship (CD, p. 6–29; Lanphear et al., 2005). They observed for this pooled dataset that the shape of the concentration-response relationship is nonlinear and the log-linear model provides a better fit over the full range of blood Pb measurements [35] than a linear one (CD, p. 6–29 and pp. 6–67 to 6–70; Lanphear et al., 2005). In addition, they found that no individual study among the seven was responsible for the estimated nonlinear relationship between Pb and deficits in IQ (CD p. 6–30). Others have also analyzed the same dataset and similarly concluded that, across the range of the dataset's blood Pb levels, a log-linear relationship was a significantly better fit than the linear relationship (p=0.009) with little evidence of residual confounding from included model variables (CD, section 6.2.13; Rothenberg and Rothenberg, 2005).

As noted in the Criteria Document, a number of examples of non- or supralinear dose-response relationships exist in toxicology (CD, pp. 6–76 and 8–38 to 8–39). With regard to the effects of Pb on neurodevelopmental outcome such as IQ, the Criteria Document suggests that initial neurodevelopmental effects at lower Pb levels may be disrupting very different biological mechanisms (*e.g.*, early developmental processes in the central nervous system) than more severe effects of high exposures that result in symptomatic Pb poisoning and frank mental retardation (CD, p. 6–76). The Criteria Document describes this issue in detail with regard to Pb (summarized in CD at p. 8–39). Various findings within the toxicological evidence, presented in the Criteria Document (described in the proposal), provide biologic plausibility for a steeper IQ loss at low blood levels, with a potential explanation being that the predominant mechanism at very low blood-Pb levels is rapidly saturated and that a different, less-rapidly-saturated process, becomes predominant at blood-Pb levels greater than 10 µg/dL.

The current evidence includes multiple studies that have examined the quantitative relationship between IQ and blood Pb level in analyses of children with individual blood Pb concentrations below 10 µg/dL. In comparing across the individual epidemiological studies and the international pooled analysis, the Criteria Document observed that at higher blood Pb levels (*e.g.*, above 10 µg/dL), the slopes (for change in IQ with blood Pb) derived for log-linear and linear models are almost identical, and for studies with lower blood Pb levels, the slopes appear to be steeper than those observed in studies involving higher blood Pb levels (CD, p. 8–78, Figure 8–7). In making these observations, the Criteria Document focused on the curves from the models from the 10th percentile to the 90th percentile saying that the ''curves are restricted to that range because log-linear curves become very steep at the lower end of the blood Pb levels, and this may be an artifact of the model chosen''.

The quantitative relationship between IQ and blood Pb level has been examined in the Criteria Document using studies where all or the majority of study subjects had blood Pb levels below 10 µg/dL and also where an analysis was performed on a subset of children whose blood Pb levels have never exceeded 10 µg/dL (CD, Table 6–1).[36] The datasets for three of these studies included concurrent blood Pb levels above 10 µg/dL; the concentration-response (C–R) relationship reported for one of the three was linear while it was log-linear for the other two. For the one study among these three that reported a linear C-R relationship, the highest blood Pb level was just below 12 µg/dL and the population mean was 7.9 µg/dL (Kordas *et al.*, 2006). Of the two studies with log-linear functions, one reported 69% of the children with blood Pb levels below 10 µg/dL and a population mean blood Pb level of 7.44 µg/dL (Al-Saleh *et al.*, 2001), and the second reported a population median blood Pb level of 9.7 µg/dL and a 95th percentile of 33.2 µg/dL (Lanphear *et al.*, 2005). In order to compare slopes across all of these studies (linear and log-linear) in the Criteria Document, EPA estimated, for each, the average slope of change in IQ with change in blood Pb between the 10th percentile [37] blood Pb level and 10 µg/dL (CD, Table 6–1). The resultant group of reported and estimated average linear slopes for IQ change with blood Pb levels up to 10 µg/dL range from -0.4 to -1.8 IQ points per µg/dL blood Pb (CD, Tables 6–1 and 8–7), with a median of -0.9 IQ points per µg/dL blood Pb (CD, p. 8–80).[38] These slopes from

[35] The median of the concurrent blood Pb levels modeled was 9.7 µg/dL; the 5th and 95th percentile values were 2.5 and 33.2 µg/dL, respectively (Lanphear *et al.,* 2005).

[36] The tests for cognitive function in these studies include age-appropriate Wechsler intelligence tests (Lanphear *et al.*, 2005; Bellinger and Needleman, 2003), the Stanford-Binet intelligence test (Canfield *et al.*, 2003), the Test of Non-Verbal Intelligence (Al-Saleh *et al.*, 2001), an abbreviated form of the Wechsler tests (Kordas *et al.*, 2006) and the Bayley Scales of Infant Development (Tellez-Rojo *et al.*, 2006). The Wechsler and Stanford-Binet tests are widely used to assess neurocognitive function in children and adults, however, these tests are not appropriate for children under age three. For such children, studies generally use the age-appropriate Bayley Scales of Infant Development as a measure of cognitive development.

[37] In the Criteria Document analysis, the 10th percentile was chosen as a common point of comparison for the loglinear (and linear) models at a point prior to the lowest end of the blood Pb levels.

[38] One of these slopes (CD, Table 6–1) is for the IQ-blood Pb (concurrent) relationship for children whose peak blood Pb levels are below 10 µg/dL in the international pooled dataset studied by Lanphear and others (2005); these authors reported this slope along with the companion slope, from the same (piece-wise) model, for the remaining children whose peak blood Pb level equals or is above 10 µg/dL (Lanphear *et al.*, 2005). In the economic analysis for EPA's recent Lead Renovation, Repair and Painting (RRP) Program rule (described above in section I.C) for children living in houses with lead-based paint, changes in IQ were estimated as a function of changes in lifetime average blood Pb level using the corresponding piece-wise model for lifetime average blood Pb derived from the pooled dataset (USEPA, 2008; USEPA, 2007d). The piecewise models that gave greater weight to impacts in this blood Pb range were chosen because peak blood Pb levels are likely to be less than 10 µg/dL for the vast majority of children exposed to Pb during renovation activities. Further, while Lanphear *et al.* (2005) used peak blood Pb concentrations to determine which segment of a model to apply, for the hypothetical children to whom the approach is discussed in the RRP Program rule, only lifetime averages were used (in the RRP analysis). To counter the impact of assigning additional hypothetical RRP children to the steeper of the two slopes than would have been the case if they could be assigned based on peak blood Pb levels (as a child's lifetime average blood Pb is lower than peak blood Pb), the RRP analysis

Continued

Tables 6–1 and 8–7 of the Criteria Document are presented in the second set of slopes in Table 1 below (adapted from Table 1 of the proposal). In this second set are studies (included in the Criteria Document Table 6–1) that examined the quantitative relationships of IQ and blood Pb in study populations for which most blood Pb levels were below 10 μg/dL and for which a linear slope restricted to blood Pb levels below about 10 μg/dL could be estimated.

Among this group of quantitative IQ-blood Pb relationships examined in the Criteria Document (CD, Tables 6–1 and 8–7), the steepest slopes for change in IQ with change in blood Pb level are those derived for the subsets of children in the Rochester and Boston cohorts for which peak blood Pb levels were <10 μg/dL; these slopes, in terms of IQ points per μg/dL blood Pb, are −1.8 (for concurrent blood Pb influence on IQ) and −1.6 (for 24-month blood Pb influence on IQ), respectively. The mean blood Pb levels for children in these subsets of the Rochester and Boston cohorts are 3.32 (Canfield, 2008) and 3.8 μg/dL (Bellinger, 2008), respectively, which are the lowest population mean levels among the datasets included in the table. Other studies with analyses involving similarly low blood Pb levels (*e.g.*, mean levels below 4 μg/dL) also had slopes steeper than −1.5 points per μg/dL blood Pb. These include the slope of −1.71 points per μg/dL blood Pb [39] for the subset of 24-month old children in the Mexico City cohort with blood Pb levels less than 5 μg/dL (n=193), for which the mean concurrent blood Pb level was 2.9 μg/dL (Tellez-Rojo *et al.* 2006, 2008),[40] and the slope of −2.94 points per μg/dL blood Pb for the subset of 6–10 year old children whose peak blood Pb levels never exceeded 7.5 μg/dL (n=112), and for which the mean concurrent blood Pb level was 3.24 μg/dL (Lanphear *et al.* 2005; Hornung 2008a). Thus, from these subset analyses, the slopes range from −1.71 to −2.94 IQ points per μg/dL of concurrent blood Pb, as shown in the first set of slopes in Table 1. In this first set are studies that included quantitative relationships for IQ and blood Pb that focused on lower individual blood Pb levels (below 7.5 μg/dL). We also note that for blood Pb levels up to approximately 3.7 μg/dL, the slope of the nonlinear C–R function in which greatest confidence is placed in estimating IQ loss in the quantitative risk assessment (the LLL function) [41] falls intermediate between these two values.

TABLE 1—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR TWO SETS OF STUDIES DISCUSSED ABOVE

Study/analysis	Study cohort	Analysis dataset	N	Range BLL [A] (μg/dL)	Geometric mean BLL [A] (μg/dL)	Form of model from which average slope derived	Average linear slope [B] (points per μg/dL)
Set of studies from which steeper slopes are drawn in the proposal							
Tellez-Rojo <5 sub-group.	Mexico City, age 24 mo.	Children—BLL<5 μg/dL.	193	0.8–4.9	2.9	Linear	−1.71
based on Lanphear et al 2005 [C], Log-linear with low-exposure linearization (LLL).	Dataset from which the log-linear function is derived is the pooled International dataset of 1333 children, age 6–10 yr, having median blood Pb of 9.7 μg/dL and 5th–95th percentile of 2.5–33.2 μg/dL.					LLL [D]: −2.29 at 2 μg/dL −1.89 at 3 μg/dL	
Lanphear et al. 2005 [C], <7.5 peak subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <7.5 μg/dL.	103	0.9–7.4	3.24	Linear	−2.94

used the piece-wise model with node at 10 μg/dL, for which the steeper of the two slopes is less steep than it is for the model with node at 7.5 μg/dL. As stated in the RRP economic analysis document, ''[s]electing a model with a node, or changing one segment to the other, at a lifetime average blood Pb concentration of 10 μg/dL rather than at 7.5 μg/dL, is a small protection against applying an incorrectly rapid change (steep slope with increasingly smaller effect as concentrations lower) to the calculation'' (USEPA, 2008). We note here that the slope for the less-than-10-μg/dL portion of the model used in the RRP analysis (-0.88) is similar to the median for the slopes included in the Criteria Document analysis of quantitative relationships for studies in which the majority of blood Pb levels were below 10 μg/dL.

[39] This slope reflects effects on cognitive development in this cohort of 24-month old children based on the age-appropriate test described earlier, and is similar in magnitude to slopes for the cohorts of older children described here. The strengths and limitations of this age-appropriate test, the Mental Development Index (MDI) of the Bayley Scales of Infant Development (BSID), were discussed in a letter to the editor by Black and Baqui (2005). The letter states that ''the MDI is a well-standardized, psychometrically strong measure of infant mental development.'' The MDI represents a complex integration of empirically-derived cognitive skills, for example, sensory/perceptual acuities, discriminations, and response; acquisition of object constancy; memory learning and problem solving; vocalization and beginning of verbal communication; and basis of abstract thinking. Black and Baqui additionally state that although the MDI is one of the most well-standardized, widely used assessment of infant mental development, evidence indicates low predictive validity of the MDI for infants younger than 24 months to subsequent measures of intelligence. They explain that the lack of continuity may be partially explained by ''the multidimensional and rapidly changing aspects of infant mental development and by variations in performance during infancy, variations in tasks used to measure intellectual functioning throughout childhood, and variations in environmental challenges and opportunities that may influence development.'' Martin and Volkmar (2007) also noted that correlations between BSID performance and subsequent IQ assessments were variable, but they also reported high test-retest reliability and validity, as indicated by the correlation coefficients of 0.83 to 0.91, as well as high interrater reliability, correlation coefficient of 0.96, for the MDI. Therefore, the BSID has been found to be a reliable indicator of current development and cognitive functioning of the infant. Martin and Volkmar (2007) further note that ''for the most part, performance on the BSID does not consistently predict later cognitive measures, particularly when socioeconomic status and level of functioning are controlled''.

[40] In this study, the slope for blood Pb levels between 5 and 10 μg/dL (population mean blood Pb of 6.9 μg/dL; n=101) was −0.94 points per μg/dL blood Pb but was not statistically significant, with a p value of 0.12. The difference in the slope between the <5 μg/dL and the 5–10 μg/dL groups was not statistically significant (Tellez-Rojo *et al.*, 2006; Tellez-Rojo, 2008).

[41] The LLL function is the loglinear function from Lampshear *et al.* (2005), with linearization at low exposures (as described in sections 2.1.5 and 4.1.1.2 ofthe Risk Assessment Report).

TABLE 1—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR TWO SETS OF STUDIES DISCUSSED ABOVE—Continued

Study/analysis	Study cohort	Analysis dataset	N	Range BLL [A] (μg/dL)	Geometric mean BLL [A] (μg/dL)	Form of model from which average slope derived	Average linear slope [B] (points per μg/dL)
Set of studies with shallower slopes (Criteria Document Table 6–1) presented in the proposal [E]							
Canfield et al 2003 [C], <10 peak subgroup.	Rochester, age 5 yr	Children—peak BLL <10 μg/dL.	71	0.5–8.4	3.32	Linear	−1.79
Bellinger and Needleman 2003 [C].	Boston [B F]	Children—peak BLL <10 μg/dL.	48	1–9.3 [F]	[F] 3.8	Linear	−1.56
Tellez-Rojo et al. 2006.	Mexico City, age 24 mo.	Full dataset	294	0.8–9.8	4.28	Linear	−1.04
Tellez-Rojo et al. 2006 full—loglinear.	Mexico City, age 24 mo.	Full dataset	294	0.8–9.8	4.28	Log-linear	[G] −0.94
Lanphear et al. 2005 [C], <10 peak [C] subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <10 μg/dL.	244	0.1–9.8	4.30	Linear	−0.80
Al-Saleh et al 2001 full—loglinear.	Saudi Arabia, age 6–12 yr.	Full dataset	533	2.3–27.36 [H]	7.44	Log-linear	[G] −0.76
Kordas et al 2006, <12 subgroup.	Torreon, Mexico, age 7 yr.	Children—BLL <12 μg/dL.	377	2.3–<12	7.9	Linear	−0.40
Lanphear et al 2005 [C] full—loglinear.	Pooled International, age 6–10 yr.	Full dataset	1333	0.1–71.7	9.7 (median)	Log-linear	[G] −0.41
Median value							[D] −0.9

[A] Blood Pb level (BLL) information provided here is drawn from publications listed in table, in some cases augmented by study authors (Bellinger, 2008; Canfield, 2008a,b; Hornung, 2008a,b; Kordas, 2008; Tellez-Rojo, 2008).
[B] Average linear slope estimates here are for relationship between IQ and concurrent blood Pb levels (BLL), except for Bellinger & Needleman which used 24 month BLLs with 10 year old IQ.
[C] The Lanphear et al. 2005 pooled International study includes blood Pb data from the Rochester and Boston cohorts, although for different ages (6 and 5 years, respectively) than the ages analyzed in Canfield et al 2003 and Bellinger and Needleman 2003.
[D] The LLL function (described in section II.C.2.b) was developed from Lanphear et al 2005 loglinear model with a linearization of the slope at BLL below 1 μg/dL. In estimating IQ loss with this function in the risk assessment (section II.A.3) the nonlinear form of the model with varying slope was used for all BLL above 1 μg/dL. The slopes shown are the average slopes (IQ points per μg/dL blood Pb) associated with application of the LLL functions from zero to the blood Pb levels identified (2 and 3 μg/dL).
[E] These studies and quantitative relationships are discussed in the Criteria Document (CD, sections 6.2, 6.2.1.3 and 8.6.2).
[F] The BLL for Bellinger and Needleman (2003) are for age 24 months.
[G] For nonlinear models, this is the estimated average slope for change in IQ with change in blood Pb over the range from the 10th percentile blood Pb value in study to 10 μg/dL (CD, p. 6–65). The shape of these models is such that the average slopes from the 10th percentiles to a value lower than 10 μg/dL are larger negative values than those shown here (e.g., the slopes to 5 μg/dL are 50% larger negative values).
[H] 69% of children in Al-Saleh *et al.* (2001) study had BLL<10 μg/dL.

3. Overview of Human Exposure and Health Risk Assessments

To put judgments about risk associated with exposure to air-related Pb in a broader public health context, EPA developed and applied models to estimate human exposures to air-related Pb and associated health risk for various air quality scenarios and alternative standards. The design and implementation of the risk assessment needed to address significant limitations and complexity that go far beyond the situation for similar assessments typically performed for other criteria pollutants. The multimedia and persistent nature of Pb and the role of multiple exposure pathways add significant complexity as compared with other criteria pollutants that focus only on the inhalation exposure. Not only was the risk assessment constrained by the timeframe allowed for this review in the context of the breadth of information to address, it was also constrained by significant limitations in data and modeling tools for the assessment, as described in section II.C.2.h of the proposal.

The scope and methodology for this assessment were developed over the last few years with considerable input from the CASAC Pb Panel and the public, as described in the proposal (section II.C.2.a).[42] The following sections provide a brief summary of the quantitative exposure and risk assessment and key findings. The complete full-scale assessment, including the associated uncertainties, is more fully summarized in section II.C of the proposal and described in detail in the Risk Assessment Report (USEPA, 2007b).

a. Design Aspects and Associated Uncertainties

As discussed in section II.C.2 of the proposal, EPA conducted exposure and risk analyses to estimate blood Pb and associated IQ loss in children exposed to air-related Pb. As recognized in section II.A.2 above and discussed in the proposal notice and Criteria Document, among the wide variety of health endpoints associated with Pb exposures, there is general consensus

[42] In their review of the final risk assessment, CASAC expressed strong support, stating that ''[t]he Final Risk Assessment report captures the breadth of issues related to assessing the potential public health risk associated with lead exposures; it competently documents the universe of knowledge and interpretations of the literature on lead toxicity, exposures, blood lead modeling and approaches for conducting risk assessments for lead'' (Henderson, 2008a, p. 4).

that the developing nervous system in children is among, if not, the most sensitive, and that neurobehavioral effects (specifically neurocognitive deficits), including IQ decrements, appear to occur at lower blood Pb levels than previously believed. The selection of children's IQ for the quantitative risk assessment reflects consideration of the evidence presented in the Criteria Document as well as advice received from CASAC (Henderson, 2006, 2007a).[43]

The brief summary provided here focuses on blood Pb and risk estimates for five case studies[44] that generally represent two types of population exposures: (1) More highly air-pathway exposed children (as described below) residing in small neighborhoods or localized residential areas with air concentrations somewhat near the standard being evaluated, and (2) location-specific urban populations with a broader range of air-related exposures.

The case studies representing the more highly air-pathway exposed children are the general urban case study and the primary Pb smelter case study. The general urban case study case study is not based on a specific geographic location and reflects several simplifications in representing exposure including uniform ambient air Pb levels associated with the standard of interest across the hypothetical study area and a uniform study population. Additionally, the method for simulating temporal variability in air Pb concentrations in this case study relied on national average estimates of the relationships between air concentrations in terms of the statistics considered for different forms of the standard being assessed and the annual ambient air concentrations required for input to the blood Pb model.[45] Thus, while this case study provides characterization of risk to children that are relatively more highly air pathway exposed (as compared to the location-specific case studies), this case study is not considered to represent a high-end scenario with regard to the characterization of ambient air Pb levels and associated risk. The primary Pb smelter case study provides risk estimates for children living in a specific area that is currently not in attainment with the current NAAQS. We have focused on a subarea within 1.5 km of the facility where airborne Pb concentrations are closest to the current standard and where children's air-related exposures are most impacted by emissions associated with the Pb smelter from which air Pb concentrations were estimated.

The three location-specific urban case studies focus on specific residential areas within Cleveland, Chicago, and Los Angeles to provide representations of urban populations with a broader range of air-related exposures due to spatial gradients in both ambient air Pb levels and population density. For example, the highest air concentrations in these case studies (*i.e.*, those closest to the standard being assessed) are found in very small parts of the study areas, while a large majority of the case study populations reside in areas with much lower air concentrations.

Based on the nature of the population exposures represented by the two categories of case study, the first category (the general urban and primary Pb smelter case studies) relates more closely to the air-related IQ loss evidence-based framework described in the proposal (sections II.D.2.a.ii and II.E.3.a) with regard to estimates of air-related IQ loss. As mentioned above, these case studies, as compared to the other category of case studies, include populations that are relatively more highly exposed by way of air pathways to air Pb concentrations somewhat near the standard level evaluated.

The air quality scenarios assessed include (a) the current NAAQS (for all five case studies);[46] (b) current conditions for the location-specific[47] and general urban case studies (which are below the current NAAQS); and (c) a range of alternate standard levels (for all case studies). The alternative NAAQS scenarios included levels of 0.50, 0.20, 0.05 and 0.02 μg/m^3, with a form of maximum monthly average, as well as a level of 0.20 μg/m^3, with a form of maximum quarterly average. Details of the assessment scenarios, including the Pb concentrations for other media are presented in Sections 2.3 and 5.1.1 of the Risk Assessment Report (USEPA, 2007b).

Exposure and associated blood Pb levels were simulated using the IEUBK model, as more fully described and presented in the Risk Assessment Report (USEPA, 2007b). Because of the nonlinear response of blood Pb to exposure and also the nonlinearity reflected in the C–R functions for estimation of IQ loss, this assessment first estimated total blood Pb and risk (air- and nonair-related), and then separated out those estimates of blood Pb and associated risk associated with the pathways of interest in this review. We separated out the estimates of total (all-pathway) blood Pb and IQ loss into a background category and two air-related categories (referred to as ''recent air'' and ''past air''). However, significant limitations in our modeling tools and data resulted in an inability to parse specific risk estimates into specific pathways, such that we have approximated estimates for the air-related and background categories.

Those Pb exposure pathways tied most directly to ambient air, which consequently have the potential to respond relatively more quickly to changes in air Pb (*i.e.*, inhalation and ingestion of indoor dust Pb derived from the infiltration of ambient air Pb indoors), were placed into the ''recent air'' category. The other air-related Pb exposure pathways, all of which are associated with atmospheric deposition, were placed into the ''past air'' category. These include ingestion of Pb in outdoor dust/soil and ingestion of the portion of Pb in indoor dust that after deposition from ambient air outdoors is carried indoors with humans (as noted in section II.A.1 above).

Among the limitations affecting our estimates for the air-related and background categories is the apportionment of background (nonair) pathways. For example, while conceptually indoor Pb paint

[43] CASAC advice on the design of the risk assessment is summarized in section II.C.2.a of the proposal.

[44] A sixth case study (the secondary Pb smelter case study) is also described in the Risk Assessment Report. However, as discussed in Section 4.3.1 of that document (USEPA, 2007a), significant limitations in the approaches have contributed to large uncertainties in the corresponding estimates.

[45] As the blood Pb model used in the risk assessment was limited in that it did not accept inputs of a temporal time step shorter than annual average, ratios of relationships in the available air monitoring data between different statistical forms being considered for the standard and an annual average were employed for the urban case studies (that did not rely on dispersion modeling) as a method of simulating the temporal variability in air Pb concentrations that occurs as a result of meteorology, source and emissions characteristics.

[46] The current NAAQS scenario for the urban case studies assumes ambient air Pb concentrations higher than those currently occurring in nearly all urban areas nationally. While it is extremely unlikely that Pb concentrations in urban areas would rise to meet the current NAAQS and there are limitations and uncertainties associated with the roll-up procedure used for the location-specific urban case studies (as described in Section II.C.2.h of the proposal), this scenario was included for those case studies to provide perspective on potential risks associated with raising levels to the point that the highest level across the study area just meets the current NAAQS. This scenario was simulated for the location-specific urban case studies using a proportional roll-up procedure. For the general urban case study, the maximum quarterly average ambient air concentration was set equal to the current NAAQS.

[47] Current conditions for the three location-specific urban case studies in terms of maximum quarterly average air Pb concentrations were 0.09, 0.14 and 0.36 μg/m^3 for the study areas in Los Angeles, Chicago and Cleveland, respectively.

contributions to indoor dust Pb would be considered background and included in the ''background'' category for this assessment, due to technical limitations related to indoor dust Pb modeling, dust from Pb paint was included as part of ''other'' indoor dust Pb (*i.e.*, as part of past air exposure). The inclusion of indoor paint Pb as a component of ''other'' indoor dust Pb (and consequently as a component of the ''past air'' category) represents a source of potential high bias in our prediction of exposure and risk associated with the ''past air'' category because conceptually, exposure to indoor paint Pb is considered part of background exposure. At the same time, Pb in ambient air does contribute to the exposure pathways included in the ''background'' category (drinking water and diet), and is likely a substantial contribution to diet (CD, p. 3–48). We could not separate the air contribution from the nonair contributions, and the total contribution from both the drinking water and diet pathways are categorized as ''background'' in this assessment. As a result, our ''background'' risk estimate includes some air-related risk representing a source of potential low bias in our predictions of air-related risk.

Further, we note that in simulating reductions in exposure associated with reducing ambient air Pb levels through alternative NAAQS (and increases in exposure if the current NAAQS was reached in certain case studies) only the exposure pathways categorized as ''recent air'' (inhalation and ingestion of that portion of indoor dust associated with outdoor ambient air) were varied with changes in air concentration. The assessment did not simulate decreases in ''past air'' exposure pathways (*e.g.*, reductions in outdoor soil Pb levels following reduction in ambient air Pb levels and a subsequent decrease in exposure through incidental soil ingestion and the contribution of outdoor soil to indoor dust).[48] These exposures were held constant across all air quality scenarios.[49]

In summary, because of limitations in the assessment design, data and modeling tools, our risk estimates for the ''past air'' category include both risks that are truly air-related and potentially, some background risk. Because we could not sharply separate Pb linked to ambient air from Pb that is background, some of the three categories of risk are underestimated and others overestimated. On balance, we believe this limitation leads to a slight overestimate of the risks in the ''past air'' category. At the same time, as discussed above, the ''recent air'' category does not fully represent the risk associated with all air-related pathways. Thus, we consider the risk attributable to air-related exposure pathways to be bounded on the low end by the risk estimated for the ''recent air'' category and on the upper end by the risk estimated for the ''recent air'' plus ''past air'' categories.

As discussed in the proposal notice and in greater detail in the Staff Paper and Risk Assessment Report, exposure and risk modeling conducted for this analysis was complex and subject to significant uncertainties due to limitations, data, models and time available. Key assumptions, limitations and uncertainties, which were recognized in various ways in the assessment and presentation of results, are listed here, beginning with those related to design of the assessment or case studies, followed by those related to estimation of Pb concentrations in ambient air, indoor dust, outdoor soil/dust, and blood, and estimation of Pb-related IQ loss.

- *Temporal Aspects:* During the 7-year exposure period, media concentrations remain fixed and the simulated child remains at the same residence (while exposure factors and physiological parameters are adjusted to match the age of the child).
- *General Urban Case Study:* The design for this case study employs assumptions regarding uniformity that are reasonable in the context of a small neighborhood population, but would contribute significant uncertainty to extrapolation of these estimates to a specific urban location, particularly a relatively large one. Thus, the risk estimates for this general urban case study, while generally representative of an urban residential population exposed to the specified ambient air Pb levels, cannot be readily related to a specific large urban population.
- *Location-Specific Urban Case Studies:* Limitations in the ambient air monitoring network limit our characterization of spatial gradients of ambient air Pb levels in these case studies.
- *Air Quality Simulation:* The proportional roll-up and roll-down procedures used in some case studies to simulate current NAAQS and alternate NAAQS levels, respectively, assume proportional changes in air concentrations across the study area in those scenarios for those case studies. EPA recognizes that it is extremely unlikely that Pb concentrations would rise to just meet the current NAAQS in urban areas nationwide and that there is substantial uncertainty with our simulation of such conditions in the urban location-specific case studies. There is also significant uncertainty in simulation conditions associated with the implementation of emissions reduction actions to meet a lower standard.
- *Outdoor Soil/Dust Pb Concentrations:* Uncertainty regarding soil/dust Pb levels and the inability to simulate the influence of changing air Pb levels related to lowering the NAAQS contributes uncertainty to air-related risk estimates.
- *Indoor Dust Pb Concentrations:* Limitations and uncertainty in modeling of indoor dust Pb levels, including the impact of reductions in ambient air Pb levels, contributes uncertainty to air-related risk estimates.
- *Interindividual Variability in Blood Pb Levels:* Uncertainty related to population variability in blood Pb levels and limitations in modeling of this introduces significant uncertainty into blood Pb and IQ loss estimates for the 95th percentile of the population.
- *Pathway Apportionment for Higher Percentile Blood Pb and IQ Loss:* Limitations in data, modeling tools and assessment design introduce uncertainty into estimates of air-related blood Pb and IQ loss for the upper ends of population distribution.
- *IQ Loss Concentration-Response Functions:* Specification of the quantitative relationship between blood Pb level and IQ loss is subject to significant uncertainty at lower blood Pb levels (*e.g.*, below 5 μg/dL concurrent blood Pb).

b. Summary of Blood Pb Estimates

Key observations regarding the blood Pb estimates from this analysis are noted here:

- As shown in Table 2 of the proposal (73 FR 29215), median blood Pb levels for the current conditions air quality scenario in the urban case studies ranged from 1.7–1.8 μg/dL for the location-specific case studies up to 1.9 μg/dL for the general urban case study. These values are slightly larger than the median value from NHANES for children aged 1–5 years old in 2003–2004 of 1.6 μg/dL (*http://www.epa.gov/envirohealth/children/body_burdens/*

[48] Similarly, since dietary Pb was included within ''background'', reductions in dietary Pb, *e.g.*, as a result of reduced deposition to crops, were also not simulated.

[49] In comparing total risk estimates between alternate NAAQS scenarios, this aspect of the analysis will tend to underestimate the reductions in risk associated with alternative NAAQS. However, this does not mean that overall risk has been underestimated. The net effect of all sources of uncertainty or bias in the analysis, which may also tend to under-or overestimate risk, could not be quantified.

b1-table.htm). Blood Pb level estimates for the 90th percentile in the urban case studies are also higher than the NHANES 90th percentile blood Pb levels. We note, however, that ambient air Pb levels in the urban case studies are higher than those at most monitoring sites in the U.S., as described in section II.C.3.a of the proposal.

• With regard to air-to-blood ratios, estimates for the general urban case study ranged from 1:2 to 1:9 with the majority of the estimates ranging from 1:4 to 1:6.[50] Because the risk assessment only reflects the impact of reductions on recent air-related pathways in predicting changes in indoor dust Pb for the general urban case study (as noted in section II.C.3.a of the proposal), however, the ratios generated are lower than they would be if they had also reflected other air-related pathways (*e.g.*, changes in outdoor surface soil/dust and dietary Pb with changes in ambient air Pb).

• Air-to-blood ratios estimated for the primary Pb smelter subarea ranged from 1:10 and higher.[51] One reason for these estimates being higher than those for the urban case study may be that the dust Pb model used may somewhat reflect ambient air-related pathways other than that of ambient air infiltrating a home.

c. Summary of IQ Loss Estimates

As described more fully in the proposal notice and in the Risk Assessment Report (USEPA, 2007b, section 5.3.1), four sets of IQ loss estimates were derived from the blood Pb estimates, one for each of four concentration-response functions derived from the international pooled analysis by Lanphear and others (2005). Each of these four functions utilizes a different approach for characterizing low-exposure IQ loss, thereby providing a range of estimates intended to reflect the uncertainty in this key aspect of the risk assessment. As described in section II.C.2.b of the proposal (and in more detail in section 2.1.5 of the Risk Assessment Report), we have placed greater confidence in the log-linear function with low-exposure linearization (LLL) and present risk estimates based on that function here.[52]

The risk estimates summarized here are those considered most relevant to the review in considering whether the current NAAQS and potential alternative NAAQS provide protection of public health with an adequate margin of safety (i.e., estimates of IQ loss associated with air-related Pb exposure). In considering these estimates, we note that IQ loss associated with air-related Pb is bounded on the low end by risk associated with the *recent air* category of exposure pathways and on the upper end by the *recent plus past air* categories of pathways (as described above in section II.A.3.a). Key observations regarding the median estimates[53] of air-related risk for the current NAAQS and alternative standards include:

• As shown in Table 2 below (Table 3 in the proposal), in all five case studies, the lower bound of population median air-related risk associated with the current NAAQS exceeds 2 points IQ loss, and the upper bound is near or above 4 points.[54]

• Alternate standards provide substantial reduction in estimates of air-related risk across the full set of alternative NAAQS considered, particularly for the lower bound of air-related risk which includes only the pathways that were varied with changes in air concentrations (as shown in Table 2).

• In the general urban case study, the estimated population median air-related risk falls between 1.9 and 3.6 points IQ loss for an alternative NAAQS of 0.50 μg/m³, maximum monthly average, between 1.2 and 3.2 points IQ loss for an alternative NAAQS of 0.20 μg/m³ and between 0.5 and 2.8 points IQ loss for an alternate NAAQS of 0.05 μg/m³, maximum monthly average, (as shown in Table 2). Higher risk estimates are associated with a maximum quarterly averaging time (USEPA, 2007b).

• At each NAAQS level assessed, the upper bound of population median air-related risk for the primary Pb smelter subarea, which due to limitations in modeling is the only air-related risk estimate for this case study, is generally higher than that for the general urban case study, likely due to differences in the indoor dust models used for the two case studies (as discussed in section II.C.3.b of the proposal).

• Compared to the other case studies, the air-related risk for the location-specific case studies is smaller because of the broader range of air-related exposures and the population distribution. For example, the majority of the populations in each of the location-specific case studies resides in areas with ambient air Pb levels well below each standard level assessed, particularly for standard levels above 0.05 μg/m³, maximum monthly average. Consequently, risk estimates for these case studies indicate little response to alternative standard levels above 0.05 μg/m³ maximum monthly average (as shown in Table 2).

TABLE 2—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED Pb EXPOSURE

NAAQS level simulated (μg/m³ max monthly, except as noted below)	Median air-related IQ loss [A]				
	General urban case study	Primary Pb smelter (sub-area) case study [B C]	Location-specific urban case studies		
			Cleveland (0.56 μg/m³)	Chicago (0.31 μg/m³)	Los Angeles (0.17 μg/m³)
1.5 max quarterly [D]	3.5–4.8 (1.5–7.7)	<6 <(3.2–9.4)	2.8–3.9 [E] (0.6–4.6)	3.4–4.7 [E] (1.4–7.4)	2.7–4.2 [E] (1.1–6.2)
0.5	1.9–3.6 (0.7–4.8)	<4.5 <(2.1–7.7)	0.6–2.9 (0.2–3.9)	([F])	([F])
0.2	1.2–3.2 (0.4–4.0)	<3.7 <(1.2–5.1)	0.6–2.8 (0.1–3.2)	0.6–2.9 (0.3–3.6)	0.7–2.9 [G] (0.2–3.5)

[50] The ratios increase as the level of the alternate standard decreases. This reflects the nonlinearity in the Pb response, which is greater on a per-unit basis for lower ambient air Pb levels.

[51] For the primary Pb smelter (full study area), for which limitations are noted in section II.C.2.c of the proposal, the air-to-blood ratio estimates, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b), ranged from 1:3 to 1:7. As in the other case studies, ratios are higher at lower ambient air Pb levels. It is noted that the underlying changes in both ambient air Pb and blood Pb across standard levels are extremely small, introducing uncertainty into ratios derived using these data.

[52] As shown in the presentation in the Staff Paper (section 4.4), risk estimates for the LLL function are generally bounded by estimates based on the other three C–R functions included in the assessment.

[53] Because of greater uncertainty in characterizing high-end population risk, and specifically related to pathway apportionment of IQ loss estimates for high-end percentiles, results discussed here focus on those for the population median.

[54] As noted in Table 2 below and sections II.C.2.d and II.C.2.h of the proposal, with regard to associated limitations and uncertainties, a proportional roll-up procedure was used to estimate air Pb concentrations in this scenario for the location-specific case studies.

TABLE 2—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED Pb EXPOSURE—Continued

NAAQS level simulated (μg/m³ max monthly, except as noted below)	Median air-related IQ loss [A]				
	General urban case study	Primary Pb smelter (sub-area) case study [B C]	Location-specific urban case studies		
			Cleveland (0.56 μg/m³)	Chicago (0.31 μg/m³)	Los Angeles (0.17 μg/m³)
0.05	0.5–2.8 (0.2–3.3)	<2.8 <(0.9–3.4)	0.1–2.6 (<0.1–3.1)	0.2–2.6 (0.1–3.2)	0.3–2.7 (0.1–3.2)
0.02	0.3–2.6 (0.1–3.1)	<2.9 <(0.9–3.3)	<0.1–2.6 (<0.1–3.0)	0.1–2.6 (<0.1–3.1)	0.1–2.6 (<0.1–3.1)

[A]—Air-related risk is bracketed by ''recent air'' (lower bound of presented range) and ''recent'' plus ''past air'' (upper bound of presented range). While differences between standard levels are better distinguished by differences in the ''recent'' plus ''past air'' estimates (upper bounds shown here), these differences are inherently underestimates. The term ''past air'' includes contributions from the outdoor soil/dust contribution to indoor dust, historical air contribution to indoor dust, and outdoor soil/dust pathways; ''recent air'' refers to contributions from inhalation of ambient air Pb or ingestion of indoor dust Pb predicted to be associated with outdoor ambient air Pb levels, with outdoor ambient air also potentially including resuspended, previously deposited Pb (see section II.C.2.e of the proposal). Boldface values are estimates generated using the log-linear with low-exposure linearization function. Values in parentheses reflect the range of estimates associated with all four concentration-response functions.

[B]—In the case of the primary Pb smelter case study, only recent plus past air estimates are available.

[B]—In the case of the primary Pb smelter case study, only recent plus past air estimates are available.

[C]—Median air-related IQ loss estimates for the primary Pb smelter (full study area) range from <1.7 to <2.9 points, with no consistent pattern across simulated NAAQS levels. This lack of a pattern reflects inclusion of a large fraction of the study population with relatively low ambient air impacts such that there is lower variation (at the population median) across standard levels (see section 4.2 of the Risk Assessment, Volume 1).

[D]—This corresponds to roughly 0.7–1.0 μg/m³ maximum monthly mean, across the urban case studies.

[E]—A ''roll-up'' was performed so that the highest monitor in the study area is increased to just meet this level.

[F]—A ''roll-up'' to this level was not performed.

[G]—A ''roll-up'' to this level was not performed; these estimates are based on current conditions in this area.

B. Need for Revision of the Current Primary Standard

The initial issue to be addressed in the current review of the primary Pb standard is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standard should be revised. In evaluating whether it is appropriate to revise the current standard, the Administrator builds on the general approach used in the initial setting of the standard, as well as that used in the last review, and reflects the broader body of evidence and information now available. The approach used is based on an integration of information on health effects associated with exposure to ambient Pb; expert judgment on the adversity of such effects on individuals; and policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety, which are informed by air quality and related analyses, quantitative exposure and risk assessments when possible, and qualitative assessment of impacts that could not be quantified. The Administrator has taken into account both evidence-based and quantitative exposure- and risk-based considerations in developing conclusions on the adequacy of the current primary Pb standard.

The Administrator's proposed conclusions on the adequacy of the current primary standard are summarized below in the Introduction (section II.B.1), followed by consideration of comments received on the proposal (section II.B.2) and the Administrator's final decision with regard to the need for revision of the current primary standard (II.B.3).

1. Introduction

As described in section II.D.1.a of the proposal, the current standard was set in 1978 to provide protection to the public, especially children as the particularly sensitive population subgroup, against Pb-induced adverse health effects (43 FR 46246). The standard was set to provide protection against anemia (as well as effects associated with higher exposures), with consideration of impacts on the heme synthesis pathway leading to anemia (43 FR 46252–46253). In setting the standard, EPA determined that ''the maximum safe level of blood lead for an individual child'' should be no higher than 30 μg/dL, and described 15 μg/dL Pb as ''the maximum safe blood lead level (geometric mean) for a population of young children'' (43 FR 46247, 46253). The basis for the level, averaging time, form and indicator are described in section II.D.1.a of the proposal.

As noted in the proposal, the body of available evidence today, summarized above in section II.A.2 and in section II.B of the proposal, and discussed in the Criteria Document, is substantially expanded from that available when the current standard was set three decades ago. The Criteria Document presents evidence of the occurrence of health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set. Further, subsequent to the setting of the standard, the Pb NAAQS criteria review during the 1980s and the current review have provided ''(a) increasingly stronger evidence that substantiatied still lower fetal and/or postnatal Pb-exposure levels (indexed by blood-Pb levels extending to as low as 10 to 15 μg/dL or, possibly, below) as being associated with slowed physical and neurobehavioral development, lower IQ, impaired learning, and/or other indicators of adverse neurological impacts; and (b) other pathophysiological effects of Pb on cardiovascular function, immune system components, calcium and vitamin D metabolism and other selected health endpoints'' (CD, pp. 8–24 to 8–25). This evidence is discussed fully in the Criteria Document.

In the proposal, EPA explained its evidence-based considerations regarding the adequacy of the current standard. With regard to the sensitive population, while the sensitivity of the elderly and other particular subgroups is recognized, as at the time the current standard was set, young children continue to be recognized as a key sensitive population for Pb exposures.

With regard to the exposure levels at which adverse health effects occur, the proposal noted that the current evidence demonstrates the occurrence of adverse health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set. This evidence is reflected in

changes over the intervening years in the CDC's identification and description of their advisory level for Pb in individual children's blood (as described above in section II.A.2.a). The current evidence indicates the occurrence of a variety of health effects, including neurological effects in children, associated with blood Pb levels extending well below 10 μg/dL (CD, sections 6.2, 8.4 and 8.5). For example, as noted in the Criteria Document with regard to the neurocognitive effects in children, the ''weight of overall evidence strongly substantiates likely occurrence of [this] type of effect in association with blood-Pb concentrations in range of 5–10 μg/dL, or possibly lower * * * Although no evident threshold has yet been clearly established for those effects, the existence of such effects at still lower blood-Pb levels cannot be ruled out based on available data.'' (CD, p. 8–61). The Criteria Document further notes that any such threshold may exist ''at levels distinctly lower than the lowest exposures examined in these epidemiological studies'' (CD, p. 8–67).

In considering the adequacy of the current standard, the Staff Paper considered the evidence in the context of the framework used to determine the standard in 1978, as adapted to reflect the current evidence. In so doing, the Staff Paper recognized that the health effects evidence with regard to characterization of a threshold for adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level. As summarized in the proposal (73 FR 29237–38) and described in the Staff Paper (section 5.4.1), parameters for this framework include estimates for average nonair blood Pb level, and air-to-blood ratio, as well as a maximum safe individual and/or geometric mean blood Pb level. For this last parameter, the Staff Paper for the purposes of this evaluation considered the lowest population mean blood Pb levels with which some neurocognitive effects have been associated in the evidence.

Based on the current evidence, the Staff Paper first concluded that young children remain the sensitive population of primary focus in this review and that ''there is now no recognized safe level of Pb in children's blood and studies appear to show adverse effects at population mean concurrent blood Pb levels as low as approximately 2 μg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000)'' (USEPA, 2007c). The Staff Paper further stated that ''while the nonair contribution to blood Pb has declined, perhaps to a range of 1.0–1.4 μg/dL, the air-to-blood ratio appears to be higher at today's lower blood Pb levels than the estimates at the time the standard was set, with current estimates on the order of 1:3 to 1:5 and perhaps up to 1:10'' (USEPA, 2007c). Adapting the framework employed in setting the standard in 1978, the Staff Paper concluded that ''the more recently available evidence suggests a level for the standard that is lower by an order of magnitude or more'' (USEPA, 2007c, p. 5–17).

Since completion of the Staff Paper and ANPR, the Agency further considered the evidence with regard to adequacy of the current standard using an approach other than the adapted 1978 framework considered in the Staff Paper. This alternative evidence-based[55] framework, referred to as the air-related IQ loss framework, shifts focus from identifying an appropriate target population mean blood lead level and instead focuses on the magnitude of effects of air-related Pb on neurocognitive functions. This framework builds on a recommendation by the CASAC Pb Panel to consider the evidence in a more quantitative manner, and is discussed in more detail in section II.E.3.a.ii of the proposal.

In this air-related IQ loss framework, EPA draws from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and population IQ loss.[56] We also draw more quantitatively from the evidence by using evidence-based C–R functions to quantify the association between air Pb concentrations and air-related population mean IQ loss. Thus, this framework more fully considers the evidence with regard to the concentration-response relationship for the effect of Pb on IQ than does the adapted 1978 framework, and it also draws from estimates for air-to-blood ratios.

In the proposal, while we noted the evidence of steeper slope for the C–R relationship for blood Pb concentration and IQ loss at lower blood Pb levels (described above in sections II.A.2.c), we stated that for purposes of consideration of the adequacy of the current standard we were concerned with the C–R relationship for blood Pb levels that would be associated with exposure to air-related Pb at the level of the current standard. For this purpose, we focused on a median linear estimate of the slope of the C–R function from study populations for which most blood Pb levels were below 10 μg/dL and for which a linear slope restricted to blood Pb levels below about 10 μg/dL could be estimated (described in CD, pp. 6–65 to 6–66 and summarized in section II.B.2.b of the proposal). The median slope estimate is −0.9 IQ points per μg/dL blood Pb (CD, p. 8–80). Applying estimates of air-to-blood ratios ranging from 1:3 to 1:5, drawing from the discussion of air-to-blood ratios in section II.B.1.c of the proposal, to a population of children exposed at the current level of the standard is estimated to result in an average air-related blood Pb level above 4 μg/dL.[57] Multiplying these blood Pb levels by the slope estimate, identified above, for blood Pb levels extending up to 10 μg/dL (−0.9 IQ points per μg/dL), would imply an average air-related IQ loss for such a group of children on the order of 4 or more IQ points.

In the proposal, EPA also explained its exposure- and risk-based considerations regarding the adequacy of the current standard. EPA estimated exposures and health risks associated with air quality that just meets the current standard (as described in the Risk Assessment Report) to help inform judgments about whether or not the current standard provides adequate protection of public health, taking into account key uncertainties associated with the estimated exposures and risks (summarized above in section II.C of the proposal and more fully in the Risk Assessment Report). In considering the adequacy of the standard, the Staff Paper considered exposure and risk estimates from the quantitative risk assessment, taking into account associated uncertainties. The Staff Paper

[55] The term ''evidence-based'' as used here refers to the drawing of information directly from published studies, with specific attention to those reviewed and described in the Criteria Document, and is distinct from considerations that draw from the results of the quantitative exposure and risk assessment.

[56] For example, as stated in the Criteria Document, ''Fortunately, there exists a large database of high quality studies on which to base inferences regarding the relationship between Pb exposure and neurodevelopment. In addition, Pb has been extensively studied in animal models at doses that closely approximate the human situation. Experimental animal studies are not compromised by the possibility of confounding by such factors as social class and correlated environmental factors. The enormous experimental animal literature that proves that Pb at low levels causes neurobehavioral deficits and provides insights into mechanisms must be considered when drawing causal inferences (Bellinger, 2004; Davis *et al.*, 1990; U.S. Environmental Protection Agency, 1986a, 1990).'' (CD, p. 6–75).

[57] This is based on the calculation in which 1.5 μg/m^3 is multiplied by a ratio of 3 μg blood Pb per 1 μg/m^3 air Pb to yield an air-related blood Pb estimates of 4.5 μg/dL; using a 1:5 ratio yields an estimate of 7.5 μg/dL. As with the 1978 framework considered in the Staff Paper, the context for use of the air-to-blood ratio here is a population being exposed at the level of the standard.

first considered exposure/risk estimates associated with air-related risk, which as recognized in section II.A.3 above (and summarized in section II.C.2.e of the proposal and described more fully in the Risk Assessment Report) are approximated estimates, provided in terms of upper and lower bounds. The Staff Paper described the magnitude of these estimates for the current NAAQS as being indicative of levels of IQ loss associated with air-related risk that may ''reasonably be judged to be highly significant from a public health perspective'' (USEPA, 2007c).

As discussed in section II.D.2.b of the proposal, the Staff Paper also describes a different risk metric that estimated differences in the numbers of children with different amounts of Pb-related IQ loss between air quality scenarios for current conditions and for the current NAAQS in the three location-specific urban case studies. The Staff Paper concluded that these estimated differences ''indicate the potential for significant numbers of children to be negatively affected if air Pb concentrations increased to levels just meeting the current standard'' (USEPA, 2007c). Beyond the findings related to quantified IQ loss, the Staff Paper recognized the potential for other, unquantified adverse effects that may occur at similarly low exposures as those quantitatively assessed in the risk assessment. In summary, the Staff Paper concluded that taken together, ''the quantified IQ effects associated with the current NAAQS and other, nonquantified effects are important from a public health perspective, indicating a need for consideration of revision of the standard to provide an appreciable increase in public health protection'' (USEPA, 2007c).

In their letter to the Administrator subsequent to consideration of the ANPR, the Staff Paper and the Risk Assessment Report, the CASAC Pb Panel advised the Administrator that they unanimously and fully supported ''Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 μg/m^3 with a monthly averaging time'' (Henderson, 2008a, p. 1). The Panel additionally advised that the current Pb NAAQS ''are totally inadequate for assuring the necessary decreases of lead exposures in sensitive U.S. populations below those current health hazard markers identified by a wealth of new epidemiological, experimental and mechanistic studies'', and that ''it is the CASAC Lead Review Panel's considered judgment that the NAAQS for Lead must be decreased to fully-protect both the health of children and adult populations'' (Henderson, 2007a, p. 5). CASAC drew support for their recommendation from the current evidence, described in the Criteria Document, of health effects occurring at dramatically lower blood Pb levels than those indicated by the evidence available when the standard was set and of a recognition of effects that extend beyond children to adults.

At the time of proposal, in considering whether the current primary standard should be revised, the Administrator carefully considered the conclusions contained in the Criteria Document, the information, exposure/risk assessments, conclusions and recommendations presented in the Staff Paper, the advice and recommendations from CASAC, and public comments received on the ANPR and other documents to date. In so doing, the Administrator noted the following: (1) A substantially expanded body of available evidence, described briefly in section II.A above and more fully in section II.B of the proposal and discussed in the Criteria Document, from that available when the current standard was set three decades ago; (2) evidence of the occurrence of health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set in 1978; (3) the currently available robust evidence of neurotoxic effects of Pb exposure in children, both with regard to epidemiological and toxicological studies; (4) associations of effects on the neurodevelopment of children with blood Pb levels notably decreased from those in the late 1970s; [58] (5) toxicological evidence including extensive experimental laboratory animal evidence that substantiates well the plausibility of the epidemiologic findings observed in human children; (6) current evidence that suggests a steeper dose-response relationship at recent lower blood Pb levels than at higher blood Pb levels, indicating the potential for greater incremental impact associated with exposure at these lower levels.

In addition to the evidence of health effects occurring at significantly lower blood Pb levels, the Administrator recognized in the proposal that, as at the time the standard was set, the current health effects evidence together with findings from the exposure and risk assessments (summarized above in section II.A.3) supports a finding that air-related Pb exposure pathways contribute to blood Pb levels in young children by inhalation and ingestion. Furthermore, the Administrator took note of the information that suggests that the air-to-blood ratio (i.e., the quantitative relationship between air concentrations and blood concentrations) is now likely larger, when air inhalation and ingestion are considered, than that estimated when the standard was set.

At the time of proposal, the Administrator first considered the current evidence in the context of an adaptation of the 1978 framework, as presented in the Staff Paper, recognizing that the health effects evidence with regard to characterization of a threshold for adverse effects has changed dramatically since the standard was set in 1978. As discussed in the proposal, however, limitations in the application of that framework to the current situation, where (unlike when the standard was set in 1978) there is not an evidentiary basis to determine a safe level for individual children with respect to the identified health effect, led the Administrator to focus primarily instead on the air-related IQ loss evidence-based framework, described in section II.D.2.a.ii of the proposal, in considering the adequacy of the current standard.

As discussed in the proposal, the Administrator judged that air-related IQ loss associated with exposure at the level of the current standard is large from a public health perspective and that this evidence-based framework supports a conclusion that the current standard does not protect public health with an adequate margin of safety. Further, the Administrator provisionally concluded that the current evidence indicates the need for a standard level that is substantially lower than the current level to provide increased public health protection, especially for at-risk groups, including most notably children, against an array of effects, most importantly including effects on the developing nervous system.

At the time of proposal, the Administrator also considered the results of the exposure and risk assessments conducted for this review as providing some further perspective on the potential magnitude of air-related IQ loss, although, noting uncertainties and limitations in the assessments, the Administrator did not place primary reliance on the exposure and risk assessments. Nonetheless, the Administrator observed that in areas projected to just meet the current standard, the quantitative estimates of

[58] As noted in the proposal (73 FR 29228), while blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels.

IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective and also recognized that, although the current monitoring data indicate few areas with airborne Pb near or just exceeding the current standard, there are significant limitations with the current monitoring network and thus there exists the potential that the prevalence of such Pb concentrations may be underestimated by currently available data.

Based on all of these considerations, the Administrator provisionally concluded that the current Pb standard is not requisite to protect public health with an adequate margin of safety because it does not provide sufficient protection, and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups.

2. Comments on the Need for Revision

In considering comments on the need for revision, the Administrator first notes the advice and recommendations from CASAC with regard to the adequacy of the current standard. In the four letters that CASAC has sent the Agency providing advice on the Pb standard, including the most recent one on the proposal, all have repeated their unanimous view regarding the need for substantial revision of the Pb NAAQS (Henderson, 2007a, 2007b, 2008a, 2008b). For example, as stated in their letter of March 2007, the ''*unanimous judgment of the Lead Panel is that * * * both the primary and secondary NAAQS should be substantially lowered*'' (Henderson, 2007a).

General comments based on relevant factors that either support or oppose any change to the current Pb primary standard are addressed in this section. Comments on elements of the proposed primary standard and on studies that relate to consideration of the appropriate indicator, averaging time and form, and level are addressed below in sections II.C.1, II.C.2, and II.C.3, respectively. Other specific comments related to the standard setting, as well as general comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standards are addressed in the Response to Comments document.

The vast majority of public comments received on the proposal generally asserted that, based on the available scientific information, the current Pb standard is insufficient to protect public health with an adequate margin of safety and revisions to the standard are appropriate. Among those calling for revisions to the current standards are medical groups, including the American Academy of Pediatrics, the American Medical Association and the American Thoracic Society, as well as two groups of concerned physicians and scientists, and the Agency's external Children's Health Protection Advisory Committee (Marty, 2008). Similar conclusions were also submitted in comments from many national, state, and local environmental and public health organizations, including, for example, the Natural Resources Defense Council (NRDC), the Sierra Club, and the Coalition to End Childhood Lead Poisoning. All of these medical, public health and environmental commenters stated that the current Pb standard needs to be revised to a level well below the current level to protect the health of sensitive population groups. Many individual commenters also expressed such views. Additionally, regional organizations of state agencies, including the National Association of Clean Air Agencies (NACAA), and Northeast States for Coordinated Air Use Management (NESCAUM) urged that EPA revise the Pb standard. State and local air pollution control authorities or public health agencies who commented on the Pb standard also supported revision of the current Pb standard, including the New York Departments of Health and Environmental Conservation, Iowa Departments of Natural Resources and Public Health, the Missouri Departments of Natural Resources and Health and Senior Services, as well as the Missouri Office of the Attorney General, among others. All tribal governments and tribal air and environmental agencies commenting on the standard, including the InterTribal Council of Arizona, Inc. (an organization of 20 tribal governments in Arizona), the Lone Pine Paiute-Shoshone Reservation, as well as the Fond du Lac Band of Lake Superior Chippewa, commented in support of revision of the Pb NAAQS.

In general, all of these commenters agreed with EPA's proposed conclusions on the importance of results from the large body of scientific studies reviewed in the Criteria Document and on the need to revise the primary Pb standard as articulated in EPA's proposal. Many commenters cited CASAC advice on this point. The EPA generally agrees with CASAC and these public commenters' conclusions regarding the need to revise the primary Pb standard. EPA agrees that the evidence assessed in the Criteria Document and the Staff Paper provides a basis for concluding that the current Pb standard does not protect public health with an adequate margin of safety. Comments on specific aspects of the level for a revised standard are discussed below in section II.C.3 below.

Some of these commenters also identified ''new'' studies that were not included in the Criteria Document as providing further support for the need to revise the Pb standards. As noted above in section I.C, as in past NAAQS reviews, the Agency is basing the final decisions in this review on the studies and related information included in the Pb air quality criteria that have undergone CASAC and public review, and will consider the newly published studies for purposes of decision making in the next Pb NAAQS review. Nonetheless, in considering these comments related to these more recent studies (further discussed in the Response to Comments document), EPA notes that our provisional consideration of these studies concludes that this new information and findings do not materially change any of the broad scientific conclusions regarding neurotoxic and other health effects of lead exposure made in the 2006 Criteria Document. For example, ''new'' studies cited by commenters on neurocognitive and neurobehavioral effects add to the overall weight of evidence and focus on findings of such effects beyond IQ in study groups with some studies including lower blood Pb levels than were available for review in the Criteria Document.

Three industry associations (National Association of Manufacturers, Non-Ferrous Founders' Society, and Wisconsin Manufacturers & Commerce) commented in support of retaining the current primary Pb standard. These commenters generally state that most health risks associated with Pb exposures are more likely to result from past air emissions or nonair sources of Pb, such as lead-based paint, and that reduction of the Pb standard will not provide meaningful benefits to public health. They additionally cite costs to those industries on whose part action will be required to meet a reduced standard. While EPA recognizes that nonair sources contribute Pb exposure to today's population, EPA disagrees with the commenters' premise that Pb exposures associated with any past air emissions are not relevant to consider in judging the adequacy of the current standard. Further, EPA disagrees with commenters, regarding the significance of health risk associated with air-related Pb exposures allowed by the current standard. As discussed in summarized in section II.B.1 above and discussed in section II.B.3 below, EPA has concluded

that the health risk associated with air-related Pb exposures allowed by the current standard is of such a significant magnitude that a revision to the standard is needed to protect public health with an adequate margin of safety. EPA further notes that, as discussed above in section I.B, under the CAA, EPA may not consider the costs of compliance in determining what standard is requisite to protect public health with an adequate margin of safety.

3. Conclusions Regarding the Need for Revision

Having carefully considered the public comments, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of Pb reached in the Criteria Document and Staff Paper, briefly summarized above in section II.B.1, remain valid. In considering whether the primary Pb standard should be revised, the Administrator places primary consideration on the large body of scientific evidence available in this review concerning the public health impacts of Pb, including significant new evidence concerning effects at blood Pb concentrations substantially below those identified when the current standard was set. As summarized in section II.A.2.b, Pb has been demonstrated to exert a broad array of adverse effects on multiple organ systems, with the evidence across this array of effects much expanded since the standard was set, with the key effects most pertinent to ambient exposures today including neurological, hematological and immune effects for children and hematological, cardiovascular and renal effects for adults. The Administrator particularly notes the robust evidence of neurotoxic effects of Pb exposure in children, both with regard to epidemiological and toxicological studies. While blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels. The toxicological evidence includes extensive experimental laboratory animal evidence that substantiates well the plausibility of the epidemiologic findings observed in human children and expands our understanding of likely mechanisms underlying the neurotoxic effects. Further, the Administrator notes the current evidence that suggests a steeper dose-response relationship at these lower blood Pb levels than at higher blood Pb levels, indicating the potential for greater incremental impact associated with exposure at these lower levels.

In addition to the evidence of health effects occurring at significantly lower blood Pb levels, the Administrator recognizes that the current health effects evidence together with findings from the exposure and risk assessments (summarized above in section II.A.3), like the information available at the time the standard was set, supports our finding that air-related Pb exposure pathways contribute to blood Pb levels in young children, by inhalation and ingestion. Furthermore, the Administrator takes note of the information that suggests that the air-to-blood ratio (i.e., the quantitative relationship between air concentrations and blood concentrations) is now likely larger, when all air inhalation and ingestion pathways are considered, than that estimated when the standard was set.

The Administrator has considered the evidence in the record, and discussed above, in the context of an adaptation of the 1978 framework, as presented in the Staff Paper, recognizing that the health effects evidence with regard to characterization of a threshold for adverse effects has changed dramatically since the standard was set in 1978. As discussed in the proposal (73 FR 29229), however, the Administrator recognizes limitations to this approach and has focused primarily instead on the air-related IQ loss evidence-based framework described in section II.B.1 above, in considering the adequacy of the current standard.

In considering the application of the air-related IQ loss framework to the current evidence as discussed above in section II.B.1, the Administrator concludes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective, and that this evidence-based framework supports a conclusion that the current standard does not protect public health with an adequate margin of safety. Further, the Administrator believes that the current evidence indicates the need for a standard level that is substantially lower than the current level to provide increased public health protection, especially for at-risk groups, including most notably children, against an array of effects, most importantly including effects on the developing nervous system.

In addition to the primary consideration given to the available evidence, the Administrator has also taken into consideration the Agency's exposure and risk assessments to help inform his evaluation of the adequacy of the current standard. As at the time of proposal, the Administrator believes the results of those assessments provide some further perspective on the potential magnitude of air-related IQ loss and thus inform his judgment on the adequacy of the current standard to protect against health effects of concern. While taking into consideration the uncertainties and limitations in the risk assessments, the Administrator again observes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb indicate risk of a magnitude that in his judgment is significant from a public health perspective. Further, although the current monitoring data indicate few areas with airborne Pb near or just exceeding the current standard, the Administrator recognizes significant limitations with the current monitoring network and thus there is the potential that the prevalence of such Pb concentrations may be underestimated by currently available data. The Administrator thus finds that the exposure and risk estimates provide additional support to the evidence-based conclusion, reached above, that the current standard needs to be revised.

Based on these considerations, and consistent with the CASAC Panel's unanimous conclusion that EPA needed to substantially lower the level of the primary Pb NAAQS to fully protect the health of children and adult populations, the Administrator agrees with the vast majority of public commenters that the current standard is not sufficient and thus not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection, especially for members of at-risk groups.

C. Conclusions on the Elements of the Standard

The four elements of the standard—indicator, averaging time, form, and level—serve to define the standard and must be considered collectively in evaluating the health and welfare protection afforded by the standard. In considering comments on the proposed revisions to the current primary Pb standard, as discussed in the following sections, EPA considers each of the four elements of the standard as to how they might be revised to provide a primary standard for Pb that is requisite to protect public health with an adequate margin of safety. The basis for the proposed decision, comments on the

proposal, and the Administrator's final decision on indicator are discussed in section II.C.1, on averaging time and form in section II.C.2, and on a level for the primary Pb NAAQS in section II.C.3.

1. Indicator

a. Basis for Proposed Decision

In setting the current standard in 1978, EPA established Pb-TSP as the indicator.[59] In comments on the 1977 proposal, EPA received comments expressing concern that because only a fraction of airborne particulate matter is respirable, an air standard based on total air Pb would be unnecessarily stringent and therefore the standard should be limited to respirable size Pb particulate matter. Such a standard might have led to a Pb NAAQS with an indicator of Pb in particulate matter less than or equal to 10 μm in diameter (Pb-PM_{10})[60] as the indicator. The Agency considered this recommendation, but did not accept it. Rather, EPA reemphasized that larger particles of air-related Pb contribute to Pb exposure through ingestion pathways, and that ingestion pathways, including those associated with deposition of Pb from the air, can be a significant component of Pb exposures. In addition to these ingestion exposure pathways, nonrespirable Pb that has been emitted to the ambient air may, at some point, become respirable through weathering or mechanical action, thus subsequently contributing to inhalation exposures. EPA concluded that total airborne Pb, both respirable and nonrespirable fractions, should be addressed by the air standard (43 FR 46251). The federal reference method (FRM) for Pb-TSP specifies the use of the high-volume sampler.

In the 1990 Staff Paper, this issue was again considered in light of information regarding limitations of the high-volume sampler used for the Pb-TSP measurements, such as the variability discussed below. The continued use of Pb-TSP as the indicator was recommended in the Staff Paper (USEPA, 1990b):

> Given that exposure to lead occurs not only via direct inhalation, but via ingestion of deposited particles as well, especially among young children, the hi-vol provides a more complete measure of the total impact of ambient air lead. * * * Despite its shortcomings, the staff believes the high-volume sampler will provide a reasonable indicator for determination of compliance * * *

As in the past, and discussed in the proposal, the evidence available today indicates that Pb in all particle size fractions, not just respirable Pb particles, contributes to Pb in blood and to associated health effects. Further, the evidence and exposure/risk estimates in the current review indicate that ingestion pathways dominate air-related exposure. Lead is unlike other criteria pollutants, where inhalation of the airborne pollutant is the key contributor to exposure. For Pb it is the quantity of Pb in ambient particles with the potential to deposit indoors or outdoors, thereby leading to a role in ingestion pathways, that is the key contributor to air-related exposure. The evidence additionally indicates that airborne Pb particles are transported long or short distances depending on their size, such that the representation of larger particles is greater at locations near sources than at sites not directly influenced by sources.

In the current review, the Staff Paper evaluated the evidence with regard to the indicator for a revised primary standard. This evaluation included consideration of the basis for using Pb-TSP as the current indicator, information regarding the sampling methodology for the current indicator, and CASAC advice with regard to indicator (described below). Based on this evaluation, the Staff Paper recommended retaining Pb-TSP as the indicator for the primary standard. The Staff Paper also recommended activities intended to encourage collection and development of datasets that will improve our understanding of national and site-specific relationships between Pb-PM_{10} (collected by low-volume sampler)[61] and Pb-TSP to support a more informed consideration of indicator during the next review. The Staff Paper suggested that such activities might include describing a federal equivalence method (FEM) in terms of PM_{10} and allowing its use for a TSP-based standard in certain situations, such as where sufficient data are available to adequately demonstrate a relationship between Pb-TSP and Pb-PM_{10} or, in combination with more limited Pb-TSP monitoring, in areas where Pb-TSP data indicate Pb levels well below the NAAQS level.

The ANPR further identified issues and options associated with consideration of the potential use of Pb-PM_{10} data for judging attainment or nonattainment with a Pb-TSP NAAQS. These issues included the impact of controlling Pb-PM_{10} for sources predominantly emitting Pb in particles larger than those captured by PM_{10} monitors (i.e., ultra-coarse)[62], and the options included potential application of Pb-PM_{10} FRM/FEMs at sites with established relationships between Pb-TSP and Pb-PM_{10}, and use of Pb-PM_{10} data, with adjustment, as a surrogate for Pb-TSP data. The ANPR broadly solicited comment in these areas.

As noted in the proposal, the Agency in setting the standard and CASAC in providing their advice (described below) both recognized that ingestion pathways are important to air-related Pb exposures and that Pb particles contributing to these pathways include ultra-coarse particles. Thus, as noted in the proposal, choosing the appropriate indicator requires consideration of the impact of the indicator on the protection provided from exposure to air-related Pb of all particle sizes, including ultra-coarse particles, by both the inhalation and ingestion pathways.

As discussed in the proposal (sections II.E.1 and V.A), the Agency recognizes the body of evidence indicating that the high-volume Pb-TSP sampling methodology contributes to imprecision in resultant Pb measurements due to variability in the efficiency of capture of particles of different sizes and thus, in the mass of Pb measured. Variability is most substantial in samples with a large portion of Pb particles greater than 10 microns, such as those samples collected near sources with emissions of ultra-coarse particles. As noted in the proposal, this variability contributes to a clear risk of underestimating the ambient level of total Pb in the air,

[59] The current standard specifies the measurement of airborne Pb with a high-volume TSP federal reference method (FRM) sampler with atomic absorption spectrometry of a nitric acid extract from the filter for Pb, or with an approved equivalent method (40 CFR 50.12, Appendix G).

[60] For simplicity, the discussion in this notice speaks as if PM_{10} samplers have a sharp size cut-off. In reality, they have a size selection behavior in which 50% of particles 10 microns in size are captured, with a progressively higher capture rate for smaller particles and a progressively lower capture rate for larger particles. The ideal capture efficiency curve for PM_{10} samplers specifies that particles above 15 microns not be captured at all, although real samplers may capture a very small percentage of particles above 15 microns. TSP samplers have 50% capture points in the range of 25 to 50 microns (Wedding *et al.*, 1977), which is broad enough to include virtually all sizes of particles capable of being transported any significant distance from their source except under extreme wind events.

[61] ''Low-volume PM_{10} sampling'' refers to sampling using any of a number of monitor models that draw 16.67 liters/minute (1 m^3/hour) of air through the filter, in contrast to ''high-volume'' sampling of either TSP or PM_{10} in which the monitor draws 1500 liters/minute (90 m^3/hour).

[62] In this notice, we use ''ultra-coarse'' to refer to particles collected by a TSP sampler but not by a PM_{10} sampler. We note that CASAC has variously also referred to these particles as ''very coarse'' or ''larger coarse-mode'' particles. This terminology is consistent with the traditional usage of ''fine'' to refer to particles collected by a $PM_{2.5}$ sampler, and ''coarse'' to refer to particles collected by a PM_{10} sampler but not by a $PM_{2.5}$ sampler, recognizing that there will be some overlap in the particle sizes in the three types of collected material.

especially in areas near sources of ultra-coarse particles, by underestimating the amount of the ultra-coarse particles. This variability also contributes to a risk of not consistently identifying sites that fail to achieve the standard.

The Agency also recognizes, as discussed in the proposal, that the low-volume PM_{10} sampling methodology does not exhibit such variability[63] due both to increased precision of the monitor and the decreased spatial variation of Pb-PM_{10} concentrations, associated with both the more widespread distribution of PM_{10} sources and aerodynamic characteristics of particles of this size class which contribute to broader distribution from sources. Accordingly, there is a lower risk of error in measuring the ambient Pb in the PM_{10} size class than there is risk of error in measuring the ambient Pb in the TSP size class using Pb TSP samplers. We additionally noted in the proposal that, since Pb-PM_{10} concentrations have less spatial variability, such monitoring data may be representative of Pb-PM_{10} air quality conditions over a larger geographic area (and larger populations) than would Pb-TSP measurements. The larger scale of representation for Pb-PM_{10} would mean that reported measurements of this indicator, and hence designation outcomes, would be less sensitive to exact monitor siting than with Pb-TSP as the indicator.

As discussed in the proposal, however, there is a different source of error associated with the use of Pb-PM_{10} as the indicator, in that larger Pb particles not captured by PM_{10} samplers would not be measured. As noted above, these particles contribute to the health risks posed by air-related Pb, especially in areas influenced by sources of ultra-coarse particles. As discussed in the proposal, there is uncertainty as to the degree to which control strategies put in place to meet a NAAQS with a Pb-PM_{10} indicator would be effective in controlling ultra-coarse Pb-containing particles. Additionally, the fraction of Pb collected with a TSP sampler that would not be collected by a PM_{10} sampler varies depending on proximity to sources of ultra-coarse Pb particles and the size mix of the particles they emit, as well as the sampling variability inherent in the method discussed above. Thus, this error is of most concern in locations in closer proximity to such sources, which may also be locations with some of the highest ambient air levels.

Accordingly, we stated in the proposal that it is reasonable to consider continued use of a Pb-TSP indicator, focusing on the fact that it specifically includes ultra-coarse Pb particles among the particles collected, all of which are of concern and need to be addressed in protecting public health from air-related exposures. We additionally recognized that some State, local, or tribal monitoring agencies, or other organizations, for the sake of the advantages noted above, and described more fully in the proposal, may wish to deploy low-volume Pb-PM_{10} samplers rather than Pb-TSP samplers. Thus, we also considered several approaches that would allow the use of Pb-PM_{10} data in conjunction with retaining Pb-TSP as the indicator. These approaches, discussed more fully in the proposal (sections II.E.1 and IV), include the development and use of site-specific scaling factors and the use of default scaling factors for particular categories of monitoring sites (e.g., source-oriented, non-source-oriented). Additionally, we solicited comment on changing the indicator to Pb in PM_{10}, in recognition of the potential benefits of such a revision discussed above.

In their advice to the Agency during the current review, the CASAC Pb Panel provided recommendations to the Agency on the indicator for a revised standard in conjunction with their recommendations for revisions to level and averaging time. As noted above in section II.B and below in section II.C.3, the Panel recommended a significant lowering of the level for the standard, which they noted would lead to a requirement for additional monitoring over that currently required, with distribution of monitors over a much larger area. In consideration of this, prior to the proposal, the CASAC Pb Panel, as well as the majority of the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee, recommended that EPA consider a change in the indicator to PM_{10}, utilizing low-volume PM_{10} sampling (Henderson, 2007a, 2007b, 2008a, 2008b; Russell, 2008a). They found support for their recommendation in a range of areas, as summarized in the proposal (73 FR 29230). In advising a revision to the indicator, CASAC also stated that they ''recognize the importance of coarse dust contributions to total Pb ingestion and acknowledge that TSP sampling is likely to capture additional very coarse particles which are excluded by PM_{10} samplers'' (Henderson 2007b). They suggested that an adjustment of the NAAQS level would accommodate the loss of these ultra-coarse Pb particles, and that development of such a quantitative adjustment might appropriately be based on concurrent Pb-PM_{10} and Pb-TSP sampling data[64] (Henderson, 2007a, 2007b, 2008a).

For reasons discussed in the proposal and recognized above, and taking into account information and assessments presented in the Criteria Document, Staff Paper, and ANPR, the advice and recommendations of CASAC and of members of the CASAC AAMM Subcommittee, and public comments received prior to proposal, the Administrator proposed to retain the current indicator of Pb-TSP, measured by the current FRM, a current FEM, or an FEM approved under the proposed revisions to 40 CFR part 53. The Administrator also proposed an expansion of the measurements accepted for determining attainment or nonattainment of the Pb NAAQS to provide an allowance for use of Pb-PM_{10} data, measured by the new low-volume Pb-PM_{10} FRM specified in the proposed appendix Q to 40 CFR part 50 or by a FEM approved under the proposed revisions to 40 CFR part 53, with site-specific scaling factors. The Administrator also solicited comment on providing States the option of using default scaling factors instead of conducting the testing that would be needed to develop the site-specific scaling factors. Additionally, the Administrator invited comment on an alternative option of revising the indicator to Pb-PM_{10}.

b. Comments on Indicator

In considering comments received on the proposal, EPA first notes the advice provided by CASAC concerning the proposal in a July 2008 letter to the Administrator (Henderson, 2008b). In that advice, CASAC repeated their prior recommendations regarding the indicator and level of the revised standard, and emphasized that these recommendations ''were based, in part on an *assumption* that the level of the primary Pb NAAQS would be 'substantially' lowered to the EPA Staff-

[63] Low-volume PM_{10} samplers are equipped with an omni-directional (cylindrical) inlet, which reduces the effect of wind direction, and a sharp particle separator which excludes most of the particles greater than 10–15 microns in diameter whose collection efficiency is most sensitive to wind speed. Also, in low-volume samplers, the filter is protected from post-sampling contamination.

[64] In their advice, CASAC recognized the potential for site-to-site variability in the relationship between Pb-TSP and Pb-PM_{10} (Henderson, 2007a, 2007b). They also stated in their September 2007 letter, ''The Panel urges that PM_{10} monitors, with appropriate adjustments, be used to supplement the data. * * * A single quantitative adjustment factor could be developed from a short period of collocated sampling at multiple sites; or PM_{10} Pb/TSP Pb 'equivalency ratio' could be determined on a regional or site-specific basis''.

recommended range (with an TSP indicator) of between 0.1 to 0.2 μg/m³ as an upper bound and 0.02 to 0.05 μg/m³ as a lower bound (with the added consideration that the selection be made somewhat 'conservatively' within this range to accommodate the potential loss of ultra-coarse lead with a PM_{10} Pb indicator)'' (emphasis in original) (Henderson, 2008b). They additionally noted that ''at most population-oriented monitoring sites, levels of PM_{10} Pb are essentially the same as TSP Pb, but at source-oriented monitoring sites with high coarse mode particulate lead emissions, TSP Pb was roughly twice as high as PM_{10} Pb'' and that this ''factor-of-two difference * * * could be readily accommodated by considering a slightly more conservative upper bound of 0.1 μg/m³ rather than 0.2 μg/m³ '' (Henderson, 2008b). The CASAC panel concluded that ''a transition to a PM_{10} indicator would be preferable, but only at a level conservatively below an upper bound of 0.2 μg/m³ or lower'' (Henderson, 2008b). EPA interprets this advice on the whole to be supportive of Pb-TSP as the indicator for any standard level greater than 0.10 μg/m³, particularly when the level has been selected with recognition of the inclusion of ultra-coarse particles in Pb-TSP measurements.

The EPA received many public comments on issues related to the indicator for Pb. The large majority of public comments were in support of EPA's proposal to retain Pb-TSP as the indicator for Pb. Represented in this group were many state agencies, as well as some Tribes and tribal environmental agencies, and local environmental agencies. Many commenters supported Pb-TSP as the indicator regardless of a level for the standard, variously citing evidence also cited by EPA in the proposal notice, such as the relevance of all sizes of Pb particles to exposures, blood Pb levels and effects and the omission of ultra-coarse particles with PM_{10} samples. In support of Pb-TSP as the indicator, a few commenters also stated that air-to-blood ratios used in the evidence-based framework for considering a level for the standard are generally based on Pb-TSP data. Some comments, similar to CASAC, supported Pb-TSP as the indicator for levels above the lower end of the proposed range (*i.e.*, above 0.10 μg/m³), including a level of 0.15 μg/m³. One commenter (NESCAUM) specifically recommended an indicator of Pb-TSP for a NAAQS with a level of 0.15 μg/m³, recommending a revision to Pb-PM_{10} only if some other, much lower, level (0.05 μg/m³) was selected.

EPA generally agrees with CASAC and the large number of public commenters with regard to the appropriateness of a Pb-TSP indicator for the level of the standard identified for the revised standard in section II.C.3 below. This conclusion is supported by the current scientific evidence, discussed above in section II.C.1.a, recognizing the range of particle sizes inclusive of ultra-coarse particles which contribute to Pb exposures, evidence of the presence of ultra-coarse particles in some areas, particularly near sources, and variation in the relationship between Pb-TSP and Pb-PM_{10} at such sites, which together contribute to uncertainty about the sufficiency of public health protection associated with a Pb-PM_{10} standard at the level of 0.15 μg/m³.

A few commenters (including the National Association of Clean Air Agencies) recommended transition to a Pb-PM_{10} indicator for the standard at levels below 0.2 μg/m³. These commenters stated that low-volume PM_{10} samplers measure Pb much more accurately than high-volume TSP samplers, referring to EPA's discussion in the proposal that recognized the variability of Pb-TSP measurements associated with wind speed and direction, and also referred to support among CASAC AAMM members and the July 2008 comments from CASAC on indicator. These commenters, however, did not provide rationales as to why a Pb-PM_{10} indicator might be justified in light of the health considerations identified by EPA in the proposal. Further, as noted above, EPA interprets CASAC's July 2008 comments on the whole to be supportive of Pb-TSP as the indicator for any standard level greater than 0.10 μg/m³.

A few commenters, including both state and industry commenters, recommended transition to Pb-PM_{10} without reference to a particular level. Some of these commenters, like CASAC, noted concerns with the high-volume TSP sampling methodology and advantages of the PM_{10} monitoring method in reduced variability of the measurements. Two industry commenters additionally suggested consideration of an indicator based on Pb-$PM_{2.5}$, stating as their rationale that almost all airborne Pb in air is in ''the small size fraction'', ambient sampling for PM_{10} and $PM_{2.5}$ size fractions is already required, and precision which might be greater with PM_{10} monitors is needed for ''lower'' standards. None of this group of commenters provided a rationale as to why a Pb-PM_{10} indicator might be justified in light of the health considerations identified by EPA in the proposal.

EPA disagrees with this group of commenters, noting the potential presence at some sites of particles that would not be captured by PM_{10} or $PM_{2.5}$ samplers yet would contribute to human exposure to Pb and associated health effects. As discussed below, EPA believes that, in light of the evidence of all particle sizes of Pb contributing to blood Pb and health effects by both ingestion and inhalation pathways, the available data on relationships between Pb-TSP and Pb-PM_{10} (discussed in section II.E.1 of the proposal and in section IV.C below) are inadequate to support development of a Pb-PM_{10}-based NAAQS that would provide sufficient but not more than necessary protection of public health, with an adequate margin of safety, across the wide variety of ambient Pb circumstances affecting this relationship, and at the level selected by the Administrator. Although, EPA did not consider relationships between Pb-TSP and Pb-$PM_{2.5}$ in the proposal, EPA notes the more restricted particle size range associated with $PM_{2.5}$ measurements than with PM_{10} measurements, and the associated omission of substantially more Pb that contributes to blood Pb and associated health effects.[65]

A number of comments were received regarding the potential use of site-specific or default scaling factors to relate Pb-PM_{10} data to a Pb-TSP-based standard, with the large majority of these comments being opposed to these options. With regard to site-specific scaling factors, commenters note the temporal variability of the relationship between Pb-TSP and Pb-PM_{10} at individual sites, raise concerns about defensibility of attainment and nonattainment decisions based on the use of scaling factors, and question whether there are benefits associated with allowance of such scaling factors.

As discussed below in section IV, EPA generally agrees with these commenters and has not adopted a provision allowing the use of site-specific scaling factors. A few commenters supported the use of default scaling factors that would be developed by EPA, as an approach that would be most easily implemented. EPA, however, concludes that the limited available data on relationships between Pb-TSP and Pb-PM_{10} are inadequate to support development of

[65] Data from collocated TSP and $PM_{2.5}$ monitors are generally presented in the Staff Paper (section 2.3.5).

appropriate default scaling factors as described below in section IV.

Although commenters generally opposed the use of scaling factors that would relate Pb-PM_{10} data to specific corresponding levels of Pb-TSP for all levels of Pb-PM_{10} and for all purposes related to implementation of the standard, many commenters supported some uses of Pb-PM_{10} monitoring with a Pb-TSP-based NAAQS. One example of such a use that was suggested by commenters is at sites well below the standard and in areas without ultra-coarse particle sources. EPA agrees with these commenters that such a limited use of Pb-PM_{10} data in such areas is desirable in light of the advantages of Pb-PM_{10} monitoring described in section II.C.1.a above, and does not raise the concerns discussed above about sufficiency of public health protection when considering ambient air Pb concentrations that are closer to the level of the standard. Such uses allowed by this rulemaking are recognized below in section II.C.1.c and discussed more fully in sections IV and V below.

Some States noted agreement with the view expressed by EPA in the proposal that low-volume TSP sampling offers advantages over high-volume TSP sampling (the federal reference method for Pb). Issues regarding the sample collection method for the TSP indicator are discussed in section V below.

c. Conclusions on Indicator

Having carefully considered the public comments, as discussed above, and advice and recommendations from CASAC on this issue, the Administrator concludes that it is appropriate to retain Pb-TSP as the indicator for the Pb NAAQS at this time. The Administrator agrees with CASAC that use of a Pb-TSP indicator is necessary to provide sufficient public health protection from the range of particle sizes of ambient air Pb, including ultra-coarse particles, in conjunction with the selected level (see section II.C.3 below). The Administrator recognizes that Pb in all particle sizes contributes to Pb in blood and associated health effects (as discussed in section II.E.1 of the proposal and II.C.1.a above). The Administrator additionally notes that selection of the standard level does not include an adjustment or accommodation for the difference in Pb particles captured by TSP and PM_{10} monitors which, as discussed elsewhere (section II.E.1 of the proposal, section II.C.1.a above, and section IV.D below) may be on the order of a factor of two in some areas. The Administrator also recognizes the quite limited dataset, particularly for source-oriented sites,[66] that is available to the Agency from which to characterize the relationship between Pb-TSP and Pb-PM_{10} for purposes of identifying the appropriate level for a Pb-PM_{10} based standard. Further, the Administrator recognizes there is uncertainty with regard to whether a Pb-PM_{10}-based NAAQS would also effectively control ultra-coarse Pb particles, which, as noted above, may have a greater presence in areas near sources where Pb concentrations are highest. In light of these considerations, the Administrator concludes that it is appropriate to retain Pb-TSP as the indicator to protect against health risks from ultra coarse particulate Pb emitted to ambient air.

With regard to the use of scaling factors to relate Pb-PM_{10} data to a Pb-TSP indicator, the Administrator concludes that the limited available data on relationships between Pb-TSP and Pb-PM_{10} are inadequate to support a use of scaling factors to relate all valid Pb-PM_{10} measurements to specific levels of Pb-TSP concentrations for all purposes of a Pb-TSP-based standard.

The Administrator concurs with the comments from CASAC and public commenters that recognize the potential value of providing a role for Pb-PM_{10} in the monitoring required for a Pb-TSP standard. Such comments emphasize the similarity of Pb-TSP and Pb-PM_{10} measurements at non-source-oriented locations, while recognizing the potential for differences at sites near sources, and recognize the sufficiency of public health protection when Pb-PM_{10} levels are well below the level of the standard. EPA believes that use of Pb-PM_{10} measurements at sites not influenced by sources of ultra-coarse Pb and where Pb concentrations are well below the standard would take advantage of the increased precision of these measurements and decreased spatial variation of Pb-PM_{10} concentrations, without raising the same concerns over a lack of protection against health risks from all particulate Pb emitted to the ambient air that support retention of Pb-TSP as the indicator. Accordingly, the Administrator is expanding the types of measurements which may be considered with regard to implementation of the Pb NAAQS. This expansion, as discussed more fully in sections IV and V below, provides a role for Pb-PM_{10} data under certain limited circumstances and with certain conditions. The circumstances and conditions under which such data are allowed, as described in sections IV and V below, are those in which the Pb concentrations are expected to be substantially below the standard and ultra-coarse particles are not expected to be present.

2. Averaging Time and Form

a. Basis for Proposed Decision

The averaging time and form of the current standard is a not-to-be-exceeded or maximum value, averaged over a calendar quarter. The basis for this averaging time and form reflects consideration of the evidence available when the Pb NAAQS were promulgated in 1978. At that time, the Agency had concluded that the level of the standard, 1.5 $\mu g/m^3$, would be a ''safe ceiling for indefinite exposure of young children'' (43 FR 46250), and that the slightly greater possibility of elevated air Pb levels for shorter periods within the quarterly averaging period, as contrasted to the monthly averaging period proposed in 1977 (43 FR 63076), was not significant for health. These conclusions were based in part on the Agency's interpretation of the health effects evidence as indicating that 30 $\mu g/dL$ was the maximum safe level of blood Pb for an individual child, and the Agency's views that the distribution of air concentrations made it unlikely there could be sustained periods greatly above the average value and that the multipathway nature of Pb exposure lessened the impact of short-term changes in air concentrations of Pb.

In the 1990 Staff Paper, this issue was again considered in light of the evidence available at that time. The 1990 Staff Paper concluded that ''[a] monthly averaging period would better capture short-term increases in lead exposure and would more fully protect children's health than the current quarterly average'' (USEPA, 1990b). The 1990 Staff Paper further concluded that ''[t]he most appropriate form of the standard appears to be the second highest monthly average in a 3-year span. This form would be nearly as stringent as a form that does not permit any exceedances and allows for discounting of one 'bad' month in 3 years which may be caused, for example, by unusual meteorology.'' In their review of the 1990 Staff Paper, the CASAC Pb Panel concurred with the staff recommendation to express the lead NAAQS as a monthly standard not to be exceeded more than once in three years.

As summarized in section II.A above and discussed in detail in the Criteria

[66] As described in the proposal (73 FR29233), collocated data from source-oriented sites were available from just three locations near three different types of sources and include data from as long ago as 1988 (Schmidt and Cavender, 2008). A limited amount of additional data has been provided in comments on the proposal.

Document, the currently available health effects evidence[67] indicates a wider variety of neurological effects, as well as immune system and hematological effects, associated with substantially lower blood Pb levels in children than were recognized when the standard was set in 1978. Further, the health effects evidence with regard to characterization of a threshold for adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level.[68]

In the proposal (section II.E.2), we noted various aspects of the current evidence that are pertinent to consideration of the averaging time and form for the Pb standard. We noted those aspects pertaining to the human physiological response to changes in Pb exposures and also aspects pertaining to the response of air-related Pb exposure pathways to changes in airborne Pb. The latter aspects are more complex for Pb than for other criteria pollutants because the exposure pathways for air-related Pb include both inhalation pathways and deposition-related ingestion pathways, which is not the case for other criteria pollutants. The persistence of Pb in multiple media and in the body[69] provides an additional complication in the case of Pb.

With regard to the human physiological response to changes in Pb exposures, as summarized in the Staff Paper and discussed in more detail in the Criteria Document, the evidence indicates that blood Pb levels respond quickly to increased Pb exposures, such that an abrupt increase in Pb uptake results in increased blood Pb levels. Contributing to this response is the absorption through the lungs and the gastrointestinal tract (which is both greater and faster in children as compared to adults), and the rapid distribution (within days), once absorbed, from plasma to red blood cells and throughout the body. As noted in the proposal, while the evidence with regard to sensitive neurological effects is limited in what it indicates regarding the specific duration of exposures associated with effects, it indicates both the sensitivity of the first three years of life and a sustained sensitivity throughout the lifespan as the human central nervous system continues to mature and be vulnerable to neurotoxicants (CD, section 8.4.2.7). In general, the evidence indicates the potential importance of exposures on the order of months (CD, section 5.3). The evidence also indicates increased vulnerability during some developmental periods (e.g., prenatal), the length of which indicates a potential importance of exposures as short as weeks to months.

As noted in the proposal with regard to the response of human exposure pathways to changes in airborne Pb, data from NHANES II and an analysis of the temporal relationship between gasoline consumption and blood Pb indicate a month lag between changes in Pb emissions from leaded gasoline and the response of children's blood Pb levels and the number of children with elevated blood Pb levels (EPA, 1986a, p. 11–39; Rabinowitz and Needleman, 1983; Schwartz and Pitcher, 1989; USEPA, 1990b). As noted in the proposal with regard to consideration of air-related Pb exposure pathways, the evidence described in the Criteria Document and the quantitative risk assessment indicate that today ingestion of dust can be a predominant exposure pathway for young children to air-related Pb. Further, the proposal noted that a recent study of dustfall near an open window in New York City indicates the potential for a response of indoor dust Pb loading to ambient airborne Pb on the order of weeks (Caravanos *et al.*, 2006; CD, p. 3–28).

In the proposal, we additionally noted that the health effects evidence identifies varying durations in exposure that may be relevant and important to the selection of averaging time. In light of uncertainties in aspects such as response times of children's exposure to airborne Pb, we recognized, as in the past, that this evidence provides a basis for consideration of both quarterly and monthly averaging times.

In considering both averaging time and form in the proposal, EPA combined the current calendar quarter averaging time with the current not-to-be exceeded (maximum) form and also combined a monthly averaging time with a second maximum form, so as to provide an appropriate degree of year-to-year stability that a maximum monthly form would not provide. We also observed in the proposal (73 FR 29235) that the second maximum monthly form provides a roughly comparable degree of protection on a broad national scale to the current maximum calendar quarter averaging time and form. This observation was based on an analysis of the 2003–2005 monitoring data set that found a roughly similar number of areas not likely to attain alternate levels of the standard for these two combinations of averaging time and form (although a slightly greater number of sites would likely exceed the levels based on the second maximum monthly average). We also noted, however, that the relative protection provided by these two averaging times and forms may differ from area to area. Moreover, we noted that control programs to reduce average Pb concentrations across a calendar quarter may not have the same protective effect as control programs aimed at reducing average Pb concentrations on a monthly basis. Given the limited scope of the current monitoring network, which lacks monitors near many significant Pb sources, and uncertainty about Pb source emissions and possible controls, the proposal noted that it is difficult to more quantitatively compare the protectiveness of standards defined in terms of the maximum calendar quarter average versus the second maximum monthly average.

In their advice to the Agency prior to the proposal, CASAC recommended that consideration be given to changing from a calendar quarter to a monthly averaging time (Henderson, 2007a, 2007b, 2008a). In making that recommendation, CASAC has emphasized support from studies that suggest that blood Pb concentrations respond at shorter time scales than would be captured completely by a quarterly average. With regard to form of the standard, CASAC has stated that one could ''consider having the lead standards based on the second highest monthly average, a form that appears to correlate well with using the maximum quarterly value'', while also indicating that ''the most protective form would be the highest monthly average in a year'' (Henderson, 2007a). Among the public comments the Agency received on the discussion of averaging time in the ANPR, the majority concurred with the CASAC recommendation for a revision to a monthly averaging time.

On an additional point related to form, the 1990 Staff Paper and the Staff Paper for this review both recommended that the Administrator consider specifying that compliance with the NAAQS be evaluated over a 3-year period. As described in the proposal, a monitor would be considered to be in violation of the NAAQS based on a 3-year period, if, in any of the three previous calendar years with sufficiently complete data (as

[67] The differing evidence and associated strength of the evidence for these different effects is described in the Criteria Document.

[68] For example, EPA recognizes today that ''there is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects'' (CD, p. 8–63).

[69] Lead accumulates in the body and is only slowly removed, with bone Pb serving as a blood PB source for years after exposure and as a source of fetal Pb exposure during pregnancy (CD, sections 4.3.1.4 and 4.3.1.5).

explained in detail in section IV of the proposal), the value of the selected averaging time and form statistic (e.g., second maximum monthly average or maximum quarterly average) exceeded the level of the NAAQS. Thus, a monitor, initially or after once having violated the NAAQS, would not be considered to have attained the NAAQS until three years have passed without the level of the standard being exceeded. In discussing the merits of this approach in the proposal, we noted that variations in Pb source emissions and in meteorological conditions contribute to the potential for a monitor to record an exceedance of a particular level in one period but not in another, even if no permanent controls have been applied to the nearby source(s). We further noted that it would potentially reduce the public health protection afforded by the standard if areas fluctuated in and out of nonattainment status so frequently that States do not have opportunity and incentive to identify sources in need of more emission control and to require those controls to be put in place. We noted that the 3-year approach would help ensure that areas initially found to be violating the NAAQS have effectively controlled the contributing lead emissions before being redesignated to attainment.

At the time of proposal, the Administrator considered the information summarized above (described in more detail in Criteria Document and Staff Paper), as well as the advice from CASAC and public comments on the ANPR. The Administrator recognized that there is support in the evidence for an averaging time as short as monthly consistent with the following observations: (1) The health evidence indicates that very short exposures can lead to increases in blood Pb levels, (2) the time period of response of indoor dust Pb to airborne Pb can be on the order of weeks, and (3) the health evidence indicates that adverse effects may occur with exposures during relatively short windows of susceptibility, such as prenatally and in developing infants.[70] The Administrator also recognized limitations and uncertainties in the evidence including the limited available evidence specific to the consideration of the particular duration of sustained airborne Pb levels having the potential to contribute to the adverse health effects identified as most relevant to this review, as well as variability in the response time of indoor dust Pb loading to ambient airborne Pb.

Based on these considerations and the air quality analyses summarized above, the Administrator concluded that this information provided support for an averaging time no longer than a calendar quarter. Further, the Administrator recognized that if substantial weight is given to the evidence of even shorter times for response of key exposure pathways, blood Pb, and associated effects to airborne Pb, a monthly averaging time may be appropriate. Accordingly, the Administrator proposed two options with regard to the form and averaging time for the standard, and with both he proposed that three years be the time period evaluated in considering attainment. One option was to retain the current not-to-be-exceeded form with an averaging time of a calendar quarter, and the second option was to revise the averaging time to a calendar month and the form to the second highest monthly average.

b. Comments on Averaging Time and Form

In considering comments on averaging time for the revised standard, the Administrator first notes that the CASAC Pb Panel, in their comments on the proposal, restated their previous recommendation to reduce the averaging time from calendar quarter to monthly (Henderson, 2008b). In repeating this recommendation in their July 2008 letter, CASAC noted that ''adverse effects could result from exposures over as few as 30 days' duration'' (Henderson, 2008b). Many public commenters also supported the option of a monthly averaging time, generally placing great weight on the recommendation of CASAC. Some of these commenters also provided additional reasons for their support for a monthly averaging time. These reasons variously included concerns regarding the lack of a ''safe'' blood Pb level; evidence that children's blood Pb concentrations respond over time periods shorter than three months; evidence for very short windows of susceptibility to some effects during prenatal and infant development; concerns that dust Pb responds relatively quickly to air Pb; and concerns for large near-source temporal variability in airborne Pb concentrations and the exposure and risk contributed by ''high'' months, which, given the persistence of Pb, may occur for some time subsequent to the ''high'' month.

Some other commenters supported retaining the current quarterly averaging time stating that the proposed option of a monthly averaging time is not well founded in the evidence. In supporting this view, the commenters variously stated that no evidence has been presented to show a relationship between a shorter-term air concentration and air-related blood Pb levels contributing to neurological effects; there is little known regarding the relationship between neurocognitive effects such as IQ and a monthly exposure period; there is uncertainty regarding the time over which indoor dust, a key pathway for air-related Pb, responds to indoor air; and, the World Health Organization and European Community air criteria or guidelines for Pb are based on a yearly average.

In considering advice from CASAC and comments from the public, EPA recognizes that the evidence indicates the potential for effects pertinent to this review to result from Pb exposures (e.g., from ingestion and inhalation routes) on the order of one to three months, as summarized in section II.C.2.a and described more fully in the proposal. EPA additionally notes the greater complexity inherent in considering the averaging time for the primary Pb standard, as compared to other criteria pollutants, due to the persistence and multimedia nature of Pb and its multiple pathways of human exposure. Accordingly, in considering averaging time in this review, in addition to considering the evidence with regard to exposure durations related to blood Pb levels associated with neurological effects, a key consideration for the Agency is how closely Pb exposures via the major air-related Pb exposure pathways reflect temporal changes in ambient air Pb concentrations, recognizing that the averaging period involves the duration over time of ambient air concentrations, and is not a direct measure of the duration or degree of exposure.

With regard to exposure durations related to blood Pb levels associated with neurocognitive effects, EPA notes that, as described in section II.A.2.c above, the concurrent blood Pb metric (i.e., blood Pb measured at the time of IQ test) has been found to have the strongest association with IQ response. Further, a concurrent blood Pb measurement is most strongly related to a child's exposure events within the past few (*e.g.*, one to three) months. This

[70] The health evidence with regard to the susceptibility of the developing fetus and infants is well documented in the evidence as described in the 1986 Criteria Document, the 1990 Supplement (e.g. chapter III) and the 2006 Criteria Document. For example, ''[n]eurobehavioral effects of Pb-exposure early in development (during fetal, neonatal, and later postnatal periods) in young infants and children ≤7 years old) have been observed with remarkable consistency across numerous studies involving varying study designs, different developmental assessment protocols, and diverse populations.'' (CD, p. E–9)

is supported by multiple aspects of the evidence (*e.g.*, CD, chapter 4; USEPA, 1986a, chapter 11), including evidence cited by CASAC and commenters, such as the findings of the significant contribution to blood Pb of gasoline Pb sales in the past month (*e.g.*, Schwartz and Pitcher, 1989; Rabinowitz and Needleman, 1983).

EPA also recognizes, as noted by some commenters and discussed in the Criteria Document and summarized in the Staff Paper, ANPR and proposal, that the evidence demonstrates sensitivity of the early years of life and increased vulnerability of specific types of effects during some developmental periods (*e.g.*, prenatal) which may be shorter than a calendar quarter. EPA notes uncertainty, however in some aspects of the linkages between airborne Pb concentrations and these physiological responses, including time-related aspects of the exposure pathways contributing to such effects.

In considering the evidence regarding how blood Pb levels respond to changes in ambient air Pb concentrations along the multiple exposure pathways to blood, EPA recognizes several pertinent aspects of the evidence. First, the evidence in this area does not specify the duration of a sustained air concentration associated with a particular blood Pb contribution. Accordingly, we are uncertain as to the precise duration of air concentration(s) reflected in any one air-to-blood ratio and the ways in which an air-to-blood ratio may vary with the duration of the air Pb concentration. However, as discussed in section II.C.2.a above, the evidence supports the importance of time periods on the order of three months or less, and as discussed below, in light of the prominent role of deposition-related pathways today, EPA concludes the evidence most strongly supports a time period of approximately three months.

Given the varying complexities of the multiple air-related exposure pathways summarized in section II.A.1 above, exposure durations pertinent for each pathway may be expected to vary. The most immediate and direct exposure pathway is the inhalation pathway, while the ingestion pathways are more indirect and to varying degrees (across the range of pathways) less immediate. For example, as mentioned above, when leaded gasoline was a predominant source of air-related exposure for people in the U.S., the evidence indicates that blood Pb levels were strongly associated with average sales of leaded gasoline during the previous month (*e.g.*, Schwartz and Pitcher, 1989). We note that exposures to the generally fine particles produced by combustion of leaded gasoline, which remain suspended in the atmosphere for many days (USEPA, 1986a, p. 5–10), provide a greater role for inhalation pathways (*e.g.*, as compared to deposition-related ingestion pathways, such as indoor dust ingestion) than would exposures to generally larger Pb particles (which tend to more readily deposit). Further, as recognized in the Staff Paper and the proposal, air-related ingestion pathways are necessarily slower to respond to changes in air concentrations than the immediate and direct pathway of inhalation. The ingestion pathways are affected by a variety of factors that play a lesser, if any, role in inhalation exposure. For example, human behavior (*e.g.*, activity, cleaning practices and frequency) and other building characteristics (*e.g.*, number of windows, presence of screens, air conditioning) would be expected to modulate the response of indoor dust to changes in ambient air Pb (Caravanos *et al.*, 2006; CD, p. 3–28).

As noted previously, the evidence and the results of the quantitative risk assessment indicate a greater role for ingestion pathways than inhalation pathways in contributing to the air-related exposures of children today. Accordingly, the relatively greater focus today (than at the time of leaded gasoline usage) on deposition-related pathways of exposure to air-related Pb such as indoor dust ingestion would tend to support consideration of an averaging time longer than a month. We additionally note results from dust Pb modeling analyses performed as part of the quantitative risk assessment. These results provide an estimate of approximately four months as the time over which an increase in air Pb will reach 90% of the final steady-state change in dust Pb (USEPA, 2007b, section G.3.2.2). Additionally, we note that multiple studies have observed blood Pb levels to exhibit seasonal patterns, perhaps related to seasonality in exposure variables (*e.g.*, Rabinowitz *et al.*, 1985).

Some commenters who supported a monthly averaging time cited concern for the potential for the occurrence of single month average air Pb concentration, within a quarter that met the standard, to be substantially above the level of the standard. For example, one commenter suggested that a monthly averaging time would be more likely to capture exceedances related to periodic activities (such as industrial activity, construction or demolition). Another commenter submitted examples of such temporal variability in ambient air concentrations at specific monitoring sites, one of which indicated a quarter in which the current standard of 1.5 $\mu g/m^3$ was met, while a single month within that quarter was some 30% percent higher (2.07 $\mu g/m^3$). In considering this example, we consider the likelihood of differing blood Pb responses between children in two different situations: one in which the 3-month average Pb concentration just met the level of the standard but a single month within the quarter was 30% higher than that level (with the other two months below the standard level), and the other in which each of three consecutive monthly average Pb concentrations just met the level of the standard. The current evidence is limited with regard to the consideration of this issue. Given the range of air-related blood Pb exposure pathways and the processes involved in their relationships with airborne Pb (*e.g.*, the response of indoor dust Pb to ambient air Pb), it is highly uncertain, based on the evidence available today, whether there would be appreciable differences in blood Pb levels between the children in these two scenarios as a result of these different 3-month periods. That is, in this example, we consider it unlikely that a single relatively higher month of air Pb followed by two months of relatively lower air Pb would translate into a similar single high month of blood Pb followed by two months of relatively low blood Pb. Rather, it is expected that the high month would tend to be modulated into a more extended and less pronounced month-to-month change in blood Pb levels.

In considering this issue, however, we recognize that greater month-to-month variability in air concentrations than that described by this example is possible, and as such variability increases, it becomes more likely that a month's air Pb concentration might result in a more pronounced impact on blood Pb concentrations.

Another example offered by the commenter described more extreme month-to-month variability in a quarter in which the current standard was met. This example indicated a monthly average that was more than 3 times the average for the quarter. The allowance for this seemingly implausible occurrence results from the current calculation method for the current quarterly average standard. The current method takes an average across all valid measurements in a quarter, without according equal weight to each month's measurements. In situations where a significantly different number of measurements occur in each month of the quarter, the current method can have the effect of giving greater weight

to multiple measurements occurring over a relatively short period. In the specific example cited by the commenter, the few very high measurements in a single month were outweighed by a much larger number of lower measurements occurring in each of the other two months of the quarter, thus biasing the resulting quarterly average. EPA agrees with the commenter that the allowance of such significant month-to-month variability within a 3-month period is inappropriate and may not provide appropriate protection of public health. In consideration of this issue, the Agency has identified changes to the method used to derive the 3-month average that would yield an average that is more representative of air quality over the 3-month period and lessen the likelihood and frequency of occurrence of cases where such extremely high months would be allowed in a 3-month averaging period that met the standard. More specifically, as discussed below in section IV, the Agency considers it appropriate to average the measurements within each month prior to deriving the 3-month average as a way to avoid the allowance of such large monthly variability as noted by the commenter.

In considering comments specifically on the current use of a block calendar quarter average, the Administrator first notes that the CASAC Pb Panel, in their comments on the proposal, stated that ''there is no logic for averaging only by 'calendar' quarter as there is nothing unique about effects that may occur exclusively during the four calendar seasons'' and that a '' 'rolling' three-month (or 90-day) average would be more logical than a 'calendar' quarter'' (Henderson, 2008b). Comments from a state environmental agency also recommended use of a 3-month rolling average, rather than the current block calendar quarter average.

EPA agrees with CASAC as to the stronger basis for a ''rolling'' 3-month average as compared to a block calendar quarter. A 3-month average not constrained to calendar quarters would consider each of the twelve 3-month periods associated with a given year, not just the four calendar years within that year. We agree with CASAC that the averaging time of calendar quarter inappropriately separates air concentrations occurring in months such as March and April that span two calendar quarters. For example, under the calendar quarter approach, two consecutive ''high'' months that occur in different calendar quarters (e.g., March and April) may be mitigated by ''low'' months in those calendar quarters (i.e., January and February for March, May and June for April). Thus, the same air quality data could cause an exceedance of the calendar quarter standard if it occurred in February and March but could meet the calendar quarter standard if it occurred in March and April. EPA believes there is no evidence-based justification for this potential disparity in outcomes. By contrast, with a rolling 3-month averaging time, each month contributes to three separate 3-month periods, through separate combinations with three different pairs of months (e.g. January-March, February-April, and March-June), thus providing a more complete consideration of air quality during that month and the periods in which it falls. EPA also notes that analyses of air quality data for 2005–2007 indicate a greater degree of protection is afforded by a rolling 3-month average as compared to a block calendar quarter average (Schmidt, 2008).

CASAC also provided advice on a form for a monthly average standard, noting that a ''monthly or 'rolling' 30-day averaging time with a 'not to be exceeded' form would be more protective against adverse short-term effects than a form (such as a 'second-highest month in three years') that periodically allows a month of exposures to much higher concentrations'' (Henderson, 2008b). Public comments also included recommendations for a not-to-be-exceeded maximum form for a monthly average (e.g., NACAA), as well as some recommendations for a second maximum monthly average (e.g., NESCAUM). While these comments are instructive on the relative merits of a maximum and a second maximum form for a monthly averaging time, given the Administrator's selection of a 3-month averaging time (as described in section II.C.2.c below), and his reasons for this selection, including his consideration of the issue of short-term changes in ambient air concentrations over the 3-month averaging time, EPA believes it is unnecessary to address comments on the appropriate form for a monthly averaging time further here.

EPA notes, however, that a maximum rolling 3-month average would be expected to provide greater protection from deposition-related pathways in an area of highly variable air concentrations than the proposed second maximum monthly average because the former does not allow for the ''discounting'' or omitting of airborne Pb in any month. While the averaging time for a maximum rolling 3-month average is longer than the monthly averaging time recommended by CASAC and several commenters, the combination of a rolling 3-month averaging time with a maximum form would be expected to offer greater protection from deposition-related exposure pathways than the proposed option of a second maximum monthly average, because each month contributes to three 3-month averages and no month is omitted from the calculation of averages for comparison to the standard. Results of analyses of air quality data for 2005–2007 are consistent with this view, in that a greater percentage of monitors meeting data completeness criteria are not likely to meet the revised standard based on a maximum rolling 3-month average as compared to a second maximum monthly average (Schmidt, 2008).[71]

More detailed responses to some of the public comments described above, as well as responses to other comments related to averaging time and form not considered here, are provided in the Response to Comments document.

c. Conclusions on Averaging Time and Form

Having carefully considered CASAC's advice and the public comments on the appropriate averaging time and form for the standard, the Administrator concludes that the fundamental scientific conclusions pertaining to averaging time described in the Criteria Document and Staff Paper, briefly summarized above in section II.C.2.a and discussed more fully in section II.E.2 of the proposal remain valid. In light of all of the evidence, the Administrator concludes that the appropriate averaging time for the standard is no longer than a 3-month period.

In considering the option of a monthly averaging time, the Administrator recognizes the complexity inherent in considering the averaging time and form for the primary Pb standard, which is greater than in the case of the other criteria pollutants, due to the multimedia nature of Pb and its multiple pathways of human exposure. Accordingly, while the Administrator recognizes there are some factors that might support a period as short as a month for the averaging time, other factors support use of a longer averaging time, as discussed in section II.C.2.b above. The Administrator believes that in the complex multimedia, multi-pathway situation for Pb, it is necessary to consider all of the relevant factors, both those pertaining to the human

[71] These analyses incorporate the revised averaging method identified above and discussed more fully in section IV below.

physiological response to changes in Pb exposures and those pertaining to the response of air-related Pb exposure pathways to changes in airborne Pb, in an integrated manner.

The Administrator recognizes that the evidence as well as the results of the quantitative risk assessment for this review indicate a greater role for ingestion pathways than inhalation pathways in contributing to children's air-related exposure. He further recognizes that ingestion pathways are influenced by more factors than inhalation pathways, and those factors are considered likely to lessen the impact of month-to-month variations in airborne Pb concentrations on levels of air-related Pb in children's blood. Accordingly, while the evidence is limited as to our ability to characterize these impacts, this evidence suggests that the multiple factors affecting ingestion pathways, such as ingestion of indoor dust, are likely to lead to response times (*e.g.,* for the response of blood to air Pb via these pathways) extending longer than a month. In addition, there remains uncertainty over the period of time needed for air Pb concentrations to lead to the health effects most at issue in this review.

Further, it is important to note, as discussed above, that a rolling 3-month averaging time is likely to be somewhat more protective from a broad national perspective than a calendar quarter averaging time. Over a 3-year time frame, the rolling 3-month averaging time is also likely to be more protective with regard to air-related Pb exposures than would be a form that allows one month in three years to be greater than the level of the standard (*i.e.,* a monthly averaging time with a second maximum form). In combination with the additional changes in form discussed below, this means that a rolling 3-month average can be expected to provide a high degree of control over all of the months of a three-year period, with few individual months exceeding the level of the standard. This expectation appears to be generally supported by analyses of air quality data for 2005–2007 comparing percentages of monitors not likely to meet a revised standard with different averaging times and forms (Schmidt, 2008).

The Administrator further notes that, as discussed in section II.C.2.b above, the rolling three-month average eliminates the possibility for two consecutive ''high'' months falling in two separate calendar quarters to be considered independently (perhaps being mitigated by ''low'' months falling in each of the same calendar quarters). Rather, the same month, in the rolling three-month approach, would contribute to three different 3-month periods through separate combinations with three different pairs of months, thus providing a more complete consideration of air quality during that month and the 3-month periods in which it falls. Taking these considerations into account, the Administrator concludes that a rolling 3-month averaging time is appropriate. This conclusion to revise from a block calendar quarter average to a rolling 3-month average is consistent with the views of CASAC and some commenters on this issue.

In recognition of the uncertainty in the information on which the decision to select a 3-month averaging time is based, the Administrator further concludes that the month-to-month variability allowed by the current method by which the 3-month average metric is derived is not sufficiently protective of public health. Accordingly, he concludes it is appropriate to modify the method by which the 3-month average metric is derived, as described in section IV below, to be the average of three monthly average concentrations, as compared to the current practice by which the average is derived across the full dataset for a quarter, without equally weighting each month within the quarter. Thus, in consideration of the uncertainty associated with the evidence pertinent to averaging time discussed above, the Administrator notes that the two changes in form for the standard (to a rolling 3-month average and to providing equal weighting to each month in deriving the 3-month average) both afford greater weight to each individual month than does the current form, tending to control both the likelihood that any month will exceed the level of the standard and the magnitude of any such exceedance.

Based on the evidence and air quality considerations discussed above, EPA concludes that a monthly averaging time is not warranted. Furthermore, the Administrator concludes that the appropriate averaging time and form for the revised primary Pb standard is a not-to-be-exceeded (maximum) 3-month rolling average evaluated over a 3-year span, derived in accordance with calculation methods described below in section IV.

3. Level

As noted in the proposal, EPA recognizes that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard. As summarized above and discussed in greater depth in the Criteria Document (CD, sections 4.3 and 6.1.3), the epidemiological evidence that associates Pb exposures with health effects generally focuses on blood Pb for the dose metric.[72] In addition, exposure to Pb comes from various media, only some of which are air-related, and through both inhalation and ingestion pathways. These complexities are in contrast to the issues faced in the reviews for other air pollutants, such as particulate matter and ozone, which involve only inhalation exposures. Further, for the health effects receiving greatest emphasis in this review (neurological effects, particularly neurocognitive and neurobehavioral effects, in children), no threshold levels can be discerned from the evidence. As was recognized at the time of the last review, estimating a threshold for toxic effects of Pb on the central nervous system entails a number of difficulties (CD, pp. 6–10 to 6–11). The task is made still more complex by support in the evidence for a nonlinear rather than linear relationship between blood Pb and neurocognitive decrement, with greater risk of decrement-associated changes per μg/dL of blood Pb at the lower levels of blood Pb in the exposed population (CD, section 6.2.13). In this context EPA notes that the health effects evidence most useful in determining the appropriate level of the NAAQS is the large body of epidemiological studies discussed in the Criteria Document. The discussion in the proposal and below therefore focuses on the epidemiological studies, recognizing and taking into consideration the complexity and resulting uncertainty in using this body of evidence to determine the appropriate level for the NAAQS.

The Administrator's proposed conclusions on range of levels for the primary standard are summarized below in the Introduction (section II.C.3.a), followed by consideration of comments received on the proposal (section II.C.3.b) and the Administrator's final decision with regard to level for the current primary standard (II.C.3.c).

a. Basis for Proposed Range

For the reasons discussed in the proposal and summarized below, and taking into account information and assessments presented in the Criteria Document, Staff Paper, and ANPR, the advice and recommendations of CASAC, and the public comments received prior to proposal, the

[72] Among the studies of Pb health effects, in which blood Pb level is generally used as an index of exposure, the sources of exposure vary and are inclusive of air-related sources of Pb such as smelters (e.g., CD, chapter 6).

Administrator proposed to revise the existing primary Pb standard. Specifically, the Administrator proposed to revise the level of the primary Pb standard, defined in terms of the current Pb-TSP indicator, to within the range of 0.10 to 0.30 μg/m^3, conditional on judgments as to the appropriate values of key parameters to use in the context of the air-related IQ loss evidence-based framework summarized below (and discussed in section II.E.3.a.ii of the proposal). Further, in recognition of alternative views of the science, the exposure and risk assessments, the uncertainties inherent in the science and these assessments, and the appropriate public health policy responses based on the currently available information, the Administrator solicited comments on alternative levels of a primary Pb-TSP standard within ranges from above 0.30 μg/m^3 up to 0.50 μg/m^3 and below 0.10 μg/m^3. In addition, the Administrator solicited comments on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero.

The Administrator's consideration of alternative levels of the primary Pb-TSP standard built on his proposed conclusion, discussed above in section II.B.1, that the overall body of evidence indicates that the current Pb standard is not requisite to protect public health with an adequate margin of safety and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups, notably including children, against an array of adverse health effects. These effects include IQ loss, decrements in other neurocognitive functions, other neurological effects and immune system effects, as well as cardiovascular and renal effects in adults, with IQ loss the health outcome quantified in the risk assessment. In reaching a proposed decision about the level of the Pb primary standard, the Administrator considered: The evidence-based considerations from the Criteria Document, Staff Paper, and ANPR, and those based on the air-related IQ loss evidence-based framework discussed in the proposal; the results of the exposure and risk assessments summarized in section II.A.3 above and in the Staff Paper, giving weight to the exposure and risk assessments as judged appropriate; CASAC advice and recommendations, as reflected in discussions of the Criteria Document, Staff Paper, and ANPR at public meetings, in separate written comments, and in CASAC's letters to the Administrator; EPA staff recommendations; and public comments received during the development of these documents, either in connection with CASAC meetings or separately. In considering what standard is requisite to protect public health with an adequate margin of safety, the Administrator noted at the time of proposal that he was mindful that this choice requires judgment based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn.

In reaching a proposed decision on a range of levels for a revised standard, as in reaching a proposed decision on the adequacy of the current standard, the Administrator primarily considered the evidence in the context of the air-related IQ loss evidence-based framework as described in the proposal (section II.E.3.a.ii). The air-related IQ loss evidence-based framework considered by the Administrator in the proposal focuses on the contribution of air-related Pb to the neurocognitive effect of IQ loss in children, with a public health goal of identifying the appropriate ambient air level of Pb to protect exposed children from health effects that are considered adverse, and are associated with their exposure to air-related Pb. In this air-related IQ loss evidence-based framework, the Agency drew from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and IQ loss in children. Building on recommendations from CASAC to consider the body of evidence in a more quantitative manner, the framework additionally draws more quantitatively from the evidence by combining air-to-blood ratios with evidence-based C–R functions from the epidemiological studies to quantify the association between air Pb concentrations and air-related population mean IQ loss in exposed children. This framework was also premised on a public health goal of selecting a proposed standard level that would prevent air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in populations of children exposed to the level of the standard. The framework explicitly links a public health goal regarding IQ loss with two key parameters—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio.

As a general matter, in considering this evidence-based framework, the Administrator recognized that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard. As discussed above, these complexities include evidence based on blood Pb as the dose metric, multimedia exposure pathways for both air-related and nonair-related Pb, and the absence of any discernible threshold levels in the health effects evidence. Further, the Administrator recognized that there are a number of important uncertainties and limitations inherent in the available health effects evidence and related information, including uncertainties in the evidence of associations between total blood Pb and neurocognitive effects in children, especially at the lowest blood Pb levels evaluated in such studies, as well as uncertainties in key parameters used in the evidence-based framework, including C–R functions and air-to-blood ratios. In addition, the Administrator recognized that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to neurocognitive effects in sensitive populations, such as IQ loss in children.

Based on the discussion of the key parameters used in the framework, as discussed in the proposal, the Administrator concluded that, in considering alternative standard levels below the level of the current standard, it was appropriate to take into account two sets of C–R functions (described in section II.E.3.a.ii of the proposal), recognizing uncertainties in the related evidence. In the proposal, the first set of C–R functions was described as reflecting the evidence indicative of steeper slopes in relationships between blood Pb and IQ in children, and the second set of C–R functions as reflecting relationships with shallower slopes between blood Pb and IQ in children.[73] In addition, the Administrator concluded that it was appropriate to consider various air-to-blood ratios within a range of values considered to be generally supported by the available evidence, again recognizing the uncertainties in the relevant evidence.[74]

[73] As described in section II.E.3.a.ii of the proposal, the first set focused on C–R functions from analyses involving population mean concurrent blood Pb levels of approximately 3 μg/dL (closer to current mean blood Pb levels in U.S. children). The second set (CD, pp. 8–78 to 8–80) considered functions descriptive of the C–R relationship from a larger set of studies that include population mean blood Pb levels ranging from a mean of 3.3 up to a median of 9.7 μg/dL (see Table 1).

[74] In considering alternative levels for the standard within the air-related IQ loss framework, the Agency focused on estimates using an air-to-

Continued

With regard to making a public health policy judgment as to the appropriate level of protection against air-related IQ loss and related effects, the Administrator first noted that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognized, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety. The NAAQS must be sufficient but not more stringent than necessary to achieve that result, and does not require a zero-risk standard. Considering the advice of CASAC and public comments on this issue, notably including the comments of the American Academy of Pediatrics (AAP, 2008), the Administrator proposed to conclude that an air-related population mean IQ loss within the range of 1 to 2 points could be significant from a public health perspective, and that a standard level should be selected to provide protection from air-related population mean IQ loss in excess of this range.

In reaching his proposed decision, the Administrator considered the application of this air-related IQ loss framework with this target degree of protection in mind, drawing from the information presented in Table 7 of the proposal (section II.E.3.a.ii) which addresses a broad range of standard levels. In so doing, the Administrator considered estimates associated with both sets of C–R functions and the range of air-to-blood ratios identified in the proposal, and noted those that would limit the estimated degree of impact on population mean IQ loss from air-related Pb to the proposed range of protection.

Taking these considerations into account, and based on the full range of information presented in Table 7 of the proposal on estimates of air-related IQ loss in children over a broad range of alternative standard levels, the Administrator concluded that it was appropriate to propose a range of standard levels, and that a range of levels from 0.10 to 0.30 μg/m^3 would be consistent with the target for protection from air-related IQ loss in children identified in the proposal. In recognition of the uncertainties in the key parameters of air-to-blood ratio and C–R functions, the Administrator stated that the selection of a standard level from within this range was conditional on judgments as to the most appropriate parameter values to use in the context of this evidence-based framework. He noted that placing more weight on the use of a C–R function with a relatively steeper slope would tend to support a standard level in the lower part of the proposed range, while placing more weight on a C–R function with a shallower slope would tend to support a level in the upper part of the proposed range. Similarly, placing more weight on a higher air-to-blood ratio would tend to support a standard level in the lower part of the proposed range, whereas placing more weight on a lower ratio would tend to support a level in the upper part of the range. In soliciting comment on a standard level within this proposed range, the Administrator specifically solicited comment on the appropriate values to use for these key parameters in the context of this evidence-based framework.

The Administrator also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of air-related IQ loss.[75] The Administrator found these quantitative assessments to provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as discussed in sections II.A.3 above and section II.E.3.b of the proposal, for purposes of evaluating potential new standards, the Administrator placed less weight on the risk estimates than on the evidence-based assessments. Nonetheless, the Administrator found the risk estimates to be roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates discussed in section II.E.3.b of the proposal, lending support to the proposed range based on this evidence-based framework.

In the proposal, the Administrator noted his view that the above considerations, taken together, provided no evidence- or risk-based bright line that indicates a single appropriate level. Instead, he noted, there is a collection of scientific evidence and judgments and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making this public health policy judgment and in selecting a standard level from a range of reasonable values. Based on consideration of the entire body of evidence and information available at the time of proposal, as well as the recommendations of CASAC and public comments, the Administrator proposed that a standard level within the range of 0.10 to 0.30 μg/m^3 would be requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. He also recognized that selection of a level from within this range was conditional on judgments as to what C–R function and what air-to-blood ratio are most appropriate to use within the context of the air-related IQ loss framework. The Administrator noted that this proposed range encompasses the specific level of 0.20 μg/m^3, the upper end of the range recommended by CASAC and by many public commenters on the ANPR. The Administrator provisionally concluded that a standard level selected from within this range would reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and cardiovascular and renal effects in adults.

The proposal noted that there is no bright line clearly directing the choice of level within this reasonable range, and therefore the choice of what is appropriate, considering the strengths and limitations of the evidence, and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments, is a public health policy judgment. To further inform this judgment, the Administrator solicited comment on the air-related IQ loss evidence-based framework considered by the Agency and on appropriate parameter values to be considered in the application of this framework. More specifically, we solicited comment on the appropriate C–R function and air-to-blood ratio to be used in the context of the air-related IQ loss framework. The Administrator also solicited comment on the degree of impact of air-related Pb on IQ loss and other related neurocognitive effects in children considered to be significant from a public health perspective, and on the use of this framework as a basis for selecting a standard level.

The Administrator further noted that the evidence-based framework, with the inputs illustrated at the time of

blood ratio of 1:5 and also provided IQ loss estimates using higher and lower estimates (i.e., 1:3 and 1:7).

[75] In considering the risk estimates in light of IQ loss estimates based on the air-related IQ loss evidence-based framework in the proposal, the Agency focused on risk estimates for the general urban and primary Pb smelter subarea case studies as these case studies generally represent population exposures for more highly air-pathway exposed children residing in small neighborhoods or localized residential areas with air concentrations nearer the standard level being evaluated, as compared to, the location-specific case studies in which populations have a broader range of air-related exposures including many well below the standard level being evaluated.

proposal, indicated that for standard levels above 0.30 μg/m³ up to 0.50 μg/m³, the estimated degree of impact on population mean IQ loss from air-related Pb would range from approximately 2 points to 5 points or more with the use of the first set of C–R functions and the full range of air-to-blood ratios considered, and would extend from somewhere within the proposed range of 1 to 2 points IQ loss to above that range when using the second set of C–R functions and the full range of air-to-blood ratios considered. The Administrator proposed to conclude in light of his consideration of the evidence in the framework discussed above that the magnitude of air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.30 up to 0.50 μg/m³ would be greater than what is requisite to protect public health with an adequate margin of safety.

In addition, the Administrator noted that for standard levels below 0.10 μg/m³, the estimated degree of impact on population mean IQ loss from air-related Pb would generally be somewhat to well below the proposed range of 1 to 2 points air-related population mean IQ loss regardless of which set of C–R functions or which air-to-blood ratio within the range of ratios considered are used. The Administrator proposed to conclude that the degree of public health protection that standards below 0.10 μg/m³ would likely afford would be greater than what is requisite to protect public health with an adequate margin of safety.

Having reached these proposed decisions based on the interpretation of the evidence, the evidence-based frameworks, the exposure/risk assessment, and the public health policy judgments described above, the Administrator recognized that other interpretations, frameworks, assessments, and judgments are possible. There are also potential alternative views as to the range of values for relevant parameters (*e.g.*, C–R function, air-to-blood ratio) in the evidence-based framework that might be considered supportable and the relative weight that might appropriately be placed on any specific value for these parameters within such ranges. In addition, the Administrator recognized that there may be other views as to the appropriate degree of public health protection that should be afforded in terms of air-related population mean IQ loss in children that would provide support for alternative standard levels different from the proposed range. Further, there may be other views as to the appropriate weight and interpretation to give to the exposure/risk assessment conducted for this review. Consistent with the goal of soliciting comment on a wide array of issues, the Administrator solicited comment on these and other issues.

In the proposal, the Administrator also recognized that Pb can be considered a non-threshold pollutant [76] and that, as discussed in section I.B above, the CAA does not require that NAAQS be established at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. However, expecting that, as time goes on, future scientific studies will continue to enhance our understanding of Pb, and that such studies might lead to a situation where there is very little if any remaining uncertainty about human health impacts from even extremely low levels of Pb in the ambient air, the Administrator recognized that there is the potential in the future for fundamental questions to arise as to how the Agency could continue to reconcile such evidence with the statutory provision calling for the NAAQS to be set at a level that is requisite to protect public health with an adequate margin of safety. In light of such considerations, EPA solicited comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero.

b. Comments on Level

In this section we discuss advice and recommendations received from CASAC and the public on the proposed range of levels for the primary Pb standard with a Pb-TSP indicator,[77] including comments on specific levels and ranges appropriate for the standard, comments pertaining to the use of the evidence-based framework and inputs to the framework, and comments related to the risk assessment. More detailed responses to some of the public comments on level described below, as well as responses to other comments related to level not discussed here, are provided in the Response to Comments document.

(i) General Comments on Range of Levels

In considering comments received on the proposal related to the standard level, EPA first notes the general advice provided by CASAC concerning the proposal in a July 2008 letter to the Administrator (Henderson, 2008b). In that letter, CASAC emphasized their unanimous recommendation (initially stated in their March 2007 letter) regarding ''*the need to substantially lower the level*'' of the primary Pb standard such that the upper bound should be ''*no higher than 0.2 μg/m³*'' (emphasis in originals).

The vast majority of public comments that addressed a level for the standard recommended standard levels below, or no higher than 0.2 μg/m³. Many of these commenters noted the advice of CASAC and recommended that EPA follow this advice. Specific rationales provided by this large group of commenters included various considerations, such as recognition that the current evidence indicates Pb effects at much lower exposure levels than when the current standard was set and in multiple systems (*e.g.*, neurological effects in children, cardiovascular and renal effects in adults), and does not indicate a threshold; impacts associated with some neurological effects can persist into adulthood; and there is now evidence of a greater air-to-blood ratio than was considered when the standard was set. Many of these commenters recommended a specific level or range of levels for the standard that was equal to or below 0.2 μg/m³. In recommending levels below 0.2 μg/m³, some of these stated that CASAC's recommendation for an upper bound of 0.2 μg/m³ should not be read to imply that CASAC supported a standard level of 0.2 μg/m³ if that level did not account for CASAC's other specific recommendations on the framework and its inputs. Some commenters' specific recommendations for level (including a standard level of 0.15 μg/m³) were based on consideration of the air-related IQ loss evidence-based framework and their application of it using their recommended parameter inputs and public health policy goal. The specific recommendations on application of the framework are discussed separately below. Some commenters (including EPA's Children's Health Protection Advisory Committee, NESCAUM, several States and Tribes, and several environmental or public health organizations) specified levels below 0.2 μg/m³ as necessary to protect public health with an adequate margin of safety, with some of these additionally

[76] Similarly, in the most recent reviews of the NAAQS for ozone and PM, EPA recognized that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level, while noting uncertainties and limitations in studies that make discerning thresholds in populations difficult (e.g., 73 FR 16444, March 27, 2008; 71 FR 61158, October 17, 2006).

[77] Some commenters provided recommendations with regard to a level for a Pb-PM_{10}-based standard. While these comments are instructive on that issue, the Administrator has decided to retain the current indicator of Pb-TSP, and therefore they do not need to be addressed here.

stating that in assuring this level of protection, EPA must take into account susceptible or vulnerable subgroups. In discussing these subgroups, some commenters noted factors such as nutritional deficiencies as contributing to susceptibility and identified minority and low-income children as a sensitive subpopulation for Pb exposures. Some of these commenters recommended much lower levels, such as 0.02 μg/m^3, based on their views as to the level needed to protect public health with an adequate margin of safety in light of their interpretation of the advice of CASAC and EPA Staff and the evidence, including the lack of identifiable threshold. Some of these commenters recommending much lower levels expressed the view that the standard should be as protective as possible.

A second, much smaller, group of comments (including some industry comments and some state agency comments), recommended levels for the standard that are higher than 0.2 μg/m^3. Among this group, some commenters provide little or no health-based rationale for their comment. Other commenters, in recommending various levels above 0.2 μg/m^3, generally state that there is no benefit to be gained by setting a lower level for the standard. In support of this general conclusion, the commenters variously stated that there is substantial uncertainty associated with the slope of the blood Pb-IQ loss concentration-response function at lower blood Pb levels, such that EPA should not rely on estimates that indicate a steeper slope at lower blood Pb levels; that the risk assessment results for total risk at alternative standard levels indicate no benefit to be achieved from a standard level below 0.5 μg/m^3; that levels derived from the evidence-based framework need upward adjustment for use with an averaging time less than a year and that IQ loss estimates derived from the evidence-based framework presented in the proposal for levels from 0.10 to 0.50 μg/m^3 do not differ much (*e.g.*, from 2 to 4.1 points IQ loss [steeper slopes] and from 1.1 to 2.2 points IQ loss [shallower slope] for the two sets of C–R functions).

For the range of reasons summarized in section II.C.3.a above, and the reasons described more fully in section II.C.3.c below, EPA does not believe that a level for the standard above 0.2 μg/m^3 would protect public health with an adequate margin of safety. Rather, EPA concludes that such a level for the standard would not be protective of public health with an adequate margin of safety. Further, EPA disagrees with the industry comment that levels identified using the evidence-based framework should be adjusted upward; this and other specific aspects of comments summarized above are discussed further in the Response to Comments document.

(ii) Use of Air-related IQ Loss Evidence-based Framework

As noted above, EPA received advice and recommendations from CASAC and comments from the public with regard to application of the air-related IQ loss evidence-based framework in the selection of a level for the primary standard. In the discussion that follows, we first describe CASAC advice and public comments on the appropriate degree of public health protection that should be afforded to at-risk populations in terms of IQ loss in children as estimated by this framework, We then describe CASAC advice and public comments on the specific parameters of C–R function and air-to-blood ratio.

In their July 2008 advice to the Agency on the proposal notice, CASAC characterized the target degree of protection proposed for use with the air-related IQ loss framework to be inadequate (Henderson, 2008a). As basis for this characterization, they repeat the advice they conveyed with their March 2007 letter, that they considered that *''a population loss of 1–2 IQ points is highly significant from a public health perspective''* and that *''the primary lead standard should be set so as to protect 99.5% of the population from exceeding that IQ loss''* (emphasis in original). They further emphasized their view that an IQ loss of 1–2 points should be ''prevented in all but a small percentile of the population—and certainly not accepted as a reasonable change in *mean* IQ scores across the entire population'' (emphasis in original).

Recommendations from several commenters, including the American Academy of Pediatrics, and state health agencies that commented on this issue, are in general agreement with the view emphasized by CASAC that air-related IQ loss of a specific magnitude, such as on the order of 1 or 2 points, should be prevented in a very high percentage (e.g., 99.5%) of the population.

EPA generally agrees with CASAC and the commenters that emphasize that the NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population. However, it is important to note that in selecting a target degree of public health protection from air-related IQ loss in children for the purposes of this review, EPA is addressing this issue more specifically in the context of this evidence-based framework. In so doing, EPA is not determining a specific quantitative public health policy goal in terms of an air-related IQ loss that is acceptable or unacceptable in the U.S. population *per se,* but instead is determining what magnitude of estimated air-related IQ loss should be used in conjunction with the specific air-related IQ loss evidence-based framework being applied in this review, recognizing the uncertainties and limitations in this framework. As discussed later, the estimated air-related IQ loss resulting from the application of this evidence-based framework should not be viewed as a bright line estimate of expected IQ loss in the population that would or would not occur. Nonetheless, these results provide a useful guide for the Administrator to use in making the basically qualitative public health policy judgment about the risk to public health that could reasonably be expected to result from exposure to the ambient air quality patterns that would be allowed by varying levels of the standard, in light of the averaging time, form, and indicator specified above.

In that context, it is important to recognize that the air-related IQ loss framework provides estimates for the mean of a subset of the population. It is an estimate for a subset of children that are assumed to be exposed to the level of the standard. The framework in effect focuses on the sensitive subpopulation that is the group of children living near sources and more likely to be exposed at the level of the standard. The evidence-based framework estimates a mean air-related IQ loss for this subpopulation of children; it does not estimate a mean for all U.S. children.

EPA is unable to quantify the percentile of the U.S. population of children that corresponds to the mean of this sensitive subpopulation. Nor is EPA confident in its ability to develop quantified estimates of air-related IQ loss for higher percentiles than the mean of this subpopulation. EPA expects that the mean of this subpopulation represents a high, but not quantifiable, percentile of the U.S. population of children. As a result, EPA expects that a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children.

One industry association commenter noted agreement with EPA's focus on population mean (or median) for the framework, and the statement of greater confidence in estimates for air-related (as contrasted with total Pb-related) IQ loss at a central point in the distribution

than at an upper percentile. This commenter also stated the view that there is likely little difference in air-related IQ loss between the mean and the upper percentiles of the exposed population, based on their interpretation of EPA risk estimates for the location-specific urban case studies. While EPA disagrees with the commenter's view and interpretation of the risk estimates from these case studies (as seen by differences in median and 95th percentile estimates presented in section 5.3.2 of the Risk Assessment Report), EPA agrees that there is a much higher level of confidence in estimates of air-related IQ loss for the mean as compared to that for an upper percentile, consistent with the Agency's recognition of such limitations in the blood Pb estimates from the risk assessment, due to limitations in the available data (as noted in section II.C.h of the proposal).

(iii) Air-to-Blood Ratio

Regarding the air-to-blood ratio, CASAC, in their July 2008 advice to the Agency on the proposal, objected to constraining the range of ratios used with the framework to the range from 1:3 to 1:7 (Henderson, 2008a). In so doing, they noted that the Staff Paper concluded that while ''there is uncertainty and variability in the absolute value of an air-to-blood relationship, the current evidence indicates a notably greater ratio [than the value of 1:2 used in 1978] * * * e.g., on the order of 1:3 to 1:10'' (USEPA, 2007, p. 5–17). With regard to the range of 1:3 to 1:7 emphasized in the proposal, CASAC stated that the lower end of the range (1:3) ''reflects the much higher air and blood levels encountered decades ago'' while ''the upper end of the range (1:7) fails to account for the higher ratios expected at lower current and future air and blood Pb levels, especially when multiple air-related lead exposure pathways are considered.'' With particular recognition of the analysis of declining blood Pb levels documented by NHANES that reflected declines in air Pb levels associated with declining use of leaded gasoline over the same period and from which CASAC notes a ratio on the order of 1:10 (Schwartz and Pitcher, 1989, as cited in Henderson, 2007a), CASAC recommended that EPA consider an air-to-blood ratio ''closer to 1:9 to 1:10 as being most reflective of current conditions'' (Henderson, 2008b).

Similar to the advice from CASAC, many commenters, including EPA's Children's Health Protection Advisory Committee, NESCAUM and Michigan Department of Environmental Quality recommended that EPA consider ratios higher than the upper end of the range used in the proposal (1:7), such as values on the order of 1:9 or 1:10 or somewhat higher and rejected the lower ratios used in the proposal as being inappropriate for application to today's children. In support of this recommendation, commenters cite ratios resulting from the study noted by CASAC (Schwartz and Pitcher, 1989), as well as others by Hayes *et al.* (1994) and Brunekreef *et al.* (1983), and also air-to-blood ratio estimates from the exposure/risk assessment.

EPA agrees with CASAC and these commenters that an upper end air-to-blood ratio of 1:7 does not give appropriate weight to the air-to-blood ratios derived from or reported by the studies by Schwartz and Pitcher (1989) and Brunekreef *et al.* (1983) [78] and on ratios derived from the risk assessment results, which extend higher than the range identified in the proposal for consideration with the framework. Accordingly, EPA agrees that the range of air-to-blood estimates appropriate for consideration in using the air-related IQ loss evidence-based framework should extend up to ratios greater than the 1:7 ratio presented as an upper end in the proposal, such that the evidence-based framework should also consider values on the order of 1:10.

Alternatively, two industry commenters supported the range presented in the proposal of 1:3 to 1:7.[79] These two and another industry commenter asserted that higher air-to-blood ratios are not supported by the evidence. Specifically, one commenter disagrees with CASAC's interpretation of the Schwartz and Pitcher (1989) study with regard to air-to-blood ratio, stating that the study indicates a potential ratio of 1:7.8, rather than 1:9 or 1:10 as stated by CASAC, and that there is a weak association between air Pb associated with leaded gasoline usage and blood Pb, making the Schwartz and Pitcher study inappropriate to consider. EPA considers both the CASAC approach and the alternate approach presented by the commenter to generally represent conceptually sound strategies for translating the relationship between gasoline usage and blood Pb (provided in the Schwartz and Pitcher, 1989 study) to air-to-blood Pb ratios. In addition, EPA notes that these approaches support both the commenters ratio of approximately 1:8 and the CASAC recommendation for EPA to use an estimate ''closer to 1:9 to 1:10''. Further, EPA disagrees with the commenter's view that the association between gasoline-related air Pb and blood Pb is weak. On the contrary, the body of evidence regarding this relationship is robust (e.g., USEPA, 1986a, sections 11.3.6 and 11.6). As stated in the 1986 Criteria Document, ''there is strong evidence that changes in gasoline lead produce large changes in blood lead'' (USEPA, 1986a, p. 11–187). Further, EPA notes that the analysis by Hayes et al. (1994), cited by the commenter as basis for their view regarding leaded gasoline, recognizes the role of leaded gasoline combustion in affecting blood Pb levels through pathways other than the inhalation pathway (e.g., via dust, soil and food pathways).[80]

Additionally, two commenters stated that the ''higher ratios'' have been generated inappropriately, citing ratios reported by Brunekreef (1984) or those derived from NHANES data (e.g., Schwartz and Pitcher, 1989 or Hayes *et al.,* 1994) as inappropriately including blood Pb not associated with air Pb concentrations in the derivation of the air-to-blood ratio. Last, two of the three industry commenters suggested that some of the air-to-blood ratios derived from the risk assessment are overstated as a result of the methodology employed.

EPA generally disagrees with these commenters' assertions that nonair sources of blood Pb are a source of bias in studies indicating ratios above 1:7 that were identified in the proposal, and emphasized by CASAC and by other commenters, as described above. For example, in section II.B.1.c of the proposal, the proposal noted ratios of 1:8.5 (Brunekreef *et al.,* 1983; Brunekreef, 1984), as well as a ratio of approximately 1:10 (presented by CASAC in consideration of Schwartz and Pitcher, 1989). In reporting these ratios, authors of these studies described how consideration was given or what adjustments were made for other sources of blood Pb, providing strength to their conclusion that the reported air-to-blood ratio reflects air Pb contributions, with little contribution from nonair sources. In addition, the study by Hilts (2003) includes an analysis that provides control for potential confounders, including

[78] EPA agrees that the study by Hayes *et al.* (1994), cited by CASAC and commenters, presents an air-to-blood ratio greater 1:10, but notes that we are not relying on this study in our decision as it has not been reviewed as part of the Criteria Document or Staff Paper (as described in Section I.C).

[79] A ratio of 1:5 was recommended by one of these commenters (Doe Run Resources Corp.).

[80] See previous footnote regarding Hayes *et al.* (1994).

alternate sources of Pb exposure, through study design (i.e., by following a similar group of children located within the same study area over a period of time). As discussed in section II.A.2.a above, the study authors report a ratio of 1:6 from this study and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7.

With regard to air-to-blood ratios derived from the risk assessment, while EPA recognizes uncertainties in these estimates, particularly those extending substantially above 1:10 (as described in the Risk Assessment Report and section II.C of the proposal), EPA disagrees with commenters' conclusions that they do not provide support for estimates on the order of 1:10.

In summary, while EPA agrees with the industry commenters that a ratio of 1:5 or 1:7.8 is supportable for use in the evidence-based framework, as noted above, EPA interprets the current evidence as providing support for use of a higher range than that described in the proposal that is inclusive at the upper end of estimates on the order of 1:10 and at the lower end on the order of 1:5. Further, EPA agrees with CASAC that the lower end of the range in the proposal, an air-to-blood ratio of 1:3, is not supported by the evidence for application to the current population of U.S. children, in light of the multiple air-related exposure pathways by which children are exposed, in addition to inhalation of ambient air, and of today's much lower air and blood Pb levels. Taking these factors into consideration, we conclude that the air-related IQ loss evidence-based framework should consider air-to-blood ratios of 1:10 at the upper end and 1:5 at the lower end.

(iv) Concentration—Response Functions

Regarding the appropriate C–R functions to consider with the evidence-based framework, CASAC, in their July 2008 advice to the Agency on the proposal notice (Henderson, 2008a), objected to EPA's consideration of C–R functions based on analyses of populations *''exhibiting much higher blood Pb levels than is appropriate for current U.S. populations''* (emphasis in original). They note that the second set of C–R functions, while including some drawn from analyses of U.S. children with mean blood Pb levels below 4 μg/dL, also includes studies with mean or median blood Pb levels ranging up to 9.7 μg/dL. Further, they emphasize that we are concerned *''with current blood Pb levels in the setting of a health-protective NAAQS, not with blood Pb levels of the past''* (emphasis in original). In conclusion, they state that ''the selection of C–R function should be based on determining which studies indicate slopes that best reflect the current, lower blood Pb levels for children in the U.S.—which, in this instance, are those studies from which *steeper* slopes are drawn'' (emphasis in original) (Henderson, 2008a).

A number of commenters (including EPA's Children's Health Protection Advisory Committee, NESCAUM and some state agencies) made recommendations with regard to C–R functions that were similar to those of CASAC. These commenters recommended consideration of C–R functions with slopes appreciably steeper than the median value representing the second set of functions in the proposal, giving greater weight to steeper slopes drawn from analyses involving children with lower blood Pb levels, closer to those of children in the U.S. today. Some of these commenters (e.g., NESCAUM) additionally suggested alternate approaches to identify a slope estimate relevant to today's blood Pb levels, considering lower blood Pb level studies across both sets of functions presented in the proposal, and to avoid placing inappropriate weight on a single highest value.

Based on the evidence described in detail in the Criteria Document and briefly summarized in section II.A.2.c above, EPA agrees with CASAC and these commenters that, given the nonlinearity of the blood Pb-IQ loss relationship (steeper slope at lower blood Pb levels), the C–R functions appropriate to use with the air-related IQ loss framework are those drawn from analyses of children with blood Pb levels closest to those of children in the U.S. today. As a result of this nonlinear relationship, a given increase in blood lead levels (e.g., 1 μg/dl of Pb) is expected to cause a greater incremental increase in adverse neurocognitive effects for a population of children with lower blood Pb levels than would be expected to occur in a population of children with higher blood Pb levels. Thus, estimates of C–R functions drawn from analyses of children with blood Pb levels that are more comparable to blood Pb levels in today's U.S. children are likely to better represent the relationship between health effects and blood Pb levels that would apply for children in the U.S. now and in the future, as compared to estimates derived from analyses of children with higher blood lead levels. As discussed in section II.A.2.a.ii above, blood Pb levels in U.S. children have declined dramatically over the past thirty years. The geometric mean blood Pb level for U.S. children aged five years and below, reported for NHANES in 2003–04 (the most recent years for which such an estimate is available), is 1.8 μg/dL and the 5th and 95th percentiles are 0.7 μg/dL and 5.1 μg/dL, respectively (Axelrad, 2008a, 2008b). The mean blood Pb levels in all of the analyses from which C–R functions were drawn and described in the proposal (presented in Table 1 of section II.A.2.c above) are higher than this U.S. mean and some are substantially higher.

In consideration of the advice from CASAC and comments from the public, we have further considered the analyses presented in Table 1 of section II.A.2.c above from which quantitative relationships between IQ loss and blood Pb levels are described in the proposal (section II.B.2.b) for the purpose of focusing on those analyses that are based on blood Pb levels that best reflect today's population of children in the U.S. Given the evidence of nonlinearity and of steeper slopes at lower blood Pb levels (summarized in section II.A.2.c above), a focus on children with appreciably higher blood Pb levels could not be expected to identify a slope estimate that would be reasonably representative for today's population of children. More specifically, in applying the evidence-based framework, we are focused on a subpopulation of U.S. children, those living near air sources and more likely to be exposed at the level of the standard. While the air-related Pb in the blood of this subpopulation is expected to be greater than that for the general population given their greater air-related Pb exposure, we do not have information on the mean total blood Pb level (or, more specifically, the nonair component) for this subpopulation. However, even if we were to assume, as an extreme hypothetical example, that the mean for the general population of U.S. children included zero contribution from air-related sources, and added that to our estimate of air-related Pb for this subpopulation, the result would still be below the lowest mean blood Pb level among the set of quantitative C–R analyses.[81] Thus, our goal in considering these quantitative analyses was to identify C–R analyses with mean blood Pb levels closest to those of today's U.S. children, including the at-risk subpopulation.[82]

[81] Using the ratio of 1:7 identified above as central within the reasonable range of air-to-blood ratios, the estimate of air-related blood Pb associated with a standard level of 0.15 μg/m^3 would be approximately 1 μg/dL. Adding this to the mean total blood Pb level for the U.S. population would yield a mean total blood Pb estimate of 2.8 μg/dL.

[82] As noted above, we also recognize that blood Pb levels are expected to further decline in response

Among the analyses presented in the proposal (Table 1), we note that six study groups from four different studies have blood Pb levels appreciably closer to the mean blood Pb levels in today's young children. Mean blood Pb levels for these study groups range from 2.9 to 4.3 μg/dL, while mean blood Pb levels for the other three study groups considered in the proposal range from 7.4 up to 9.7 μg/dL. Further, among the six slopes from analyses with blood Pb levels closest to today's blood Pb levels, four come from two studies, with these two studies each providing two analyses of differing blood Pb levels. Focusing on the single analysis from each of the four studies that has a mean blood Pb level closest to today's mean for U.S. children yields four slopes ranging from −1.56 to −2.94, with a median of −1.75 IQ points per μg/dL (Table 3). Consistent with the evidence for nonlinearity in the C–R relationship, the slopes for the C–R functions from these four analyses are steeper than the slopes for the other higher blood Pb level analyses. In considering the C–R functions from these four analyses with the air-related IQ loss framework in section II.C.3.c below, we have placed greater weight on the median of the group, giving less weight to the minimum or maximum values, recognizing the uncertainty in determining the C–R relationship.

TABLE 3—SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD Pb FOR ANALYSES WITH BLOOD Pb LEVELS CLOSEST TO THOSE OF CHILDREN IN THE U.S. TODAY

Blood Pb levels (μg/dL)		Study/analysis	Average linear slope [A] (IQ points per μg/dL)
Geometric mean	Range (min–max)		
2.9	0.8–4.9	Tellez-Rojo et al. 2006, <5 subgroup	−1.71
3.24	0.9–7.4	Lanphear et al. 2005 [B], <7.5 peak subgroup	−2.94
3.32	0.5–8.4	Canfield et al. 2003 [B], <10 peak subgroup	−1.79
3.8	1–9.3	Bellinger and Needleman 2003 [B], <10 peak subgroup	−1.56
Median value			−1.75

[A] Average linear slope estimates here are for relationship between IQ and concurrent blood Pb levels except for Bellinger & Needleman for which study reports relationship for 10-year-old IQ with 24-month blood Pb levels.

[B] The Lanphear et al. (2005) pooled International study includes blood Pb data from the Rochester and Boston cohorts, although for different ages (6 and 5 years, respectively) than the ages analyzed in Canfield *et al.* (2003) and Bellinger and Needleman (2003).

Some commenters representing a business or industry association recommended that EPA rely on the median estimate from the second set of C–R functions presented in the proposal. As their basis for this view, these commenters made several points. For example, they stated that the extent and magnitude of nonlinearity in the IQ-blood Pb C–R relationship is ''highly uncertain,'' and as part of their rationale for this statement they cited studies by Jusko *et al.* (2007) and Surkan *et al.* (2007) as not providing support for a nonlinear C–R function. Other statements made by these commenters in support of their view are that the maximum slope in the first set is an ''outlier,'' that the second set reflects a greater number of studies and subjects than the first set, and that simply being closer to the blood Pb levels of today's children does not provide a better estimate than the median of the second set, with some noting that the second set is inclusive of some analyses with blood Pb levels similar to those in first set.

EPA disagrees with these commenters' view that a focus on analyses of children with blood Pb levels closer to today's children is not an important criterion for selecting a C–R function for use with the IQ loss framework. On the contrary, as stated above, EPA agrees with CASAC that this is an essential criterion for this analysis. While EPA recognizes uncertainty in the quantitative characterization of the nonlinearity in the blood Pb-IQ loss relationship, the weight of the current evidence (described in detail in the Criteria Document) supports our conclusion that the blood Pb-IQ loss relationship is nonlinear, with steeper slopes at lower blood Pb levels. While EPA agrees there are a greater number of studies and subjects in the second set, the nonlinearity of the relationship at issue means that a focus on C–R functions from the studies in that set involving children with appreciably higher blood Pb levels could not be expected to identify a slope estimate that would be reasonably representative for today's population of children. In reviewing the available studies with this important criterion in mind, as described above, we have identified four different studies from which C–R functions can be drawn, and in considering these functions in the context of the air-related IQ loss framework, have focused on the median estimate for the group, consequently avoiding focus on a single estimate that may be unduly influenced by one single analysis.

With regard to the ''new'' studies cited by commenters above, EPA notes that we are not relying on them in this review for the reasons stated above in section I.C. After provisional consideration of these studies cited by commenters (discussed further in the Response to Comments document), EPA has determined that the more recent cited studies provide only limited information with regard to the shape of the C–R curve and, in light of other recent provisionally considered studies and those studies reviewed in the Criteria Document, do not materially change EPA's conclusion regarding nonlinearity that is well founded in the evidence described in the Criteria Document.

(v) Role of Risk Assessment

Some commenters recommended that the Administrator place greater weight on the risk estimates derived in the quantitative risk assessment, with some (e.g., the Association of Battery Recyclers) concluding that these estimates supported a level for the standard above the proposed range and some (e.g., NRDC and Missouri Coalition for the Environment) concluding that they supported a level at the lower end or below the proposed range. For the reasons identified in the

to this and other public health protection actions, including those described above in section I.D.

proposal and noted in section II.C.3.c below, the Administrator has placed primary weight on the air-related IQ loss evidence-based framework in his decision with regard to level, and less weight on risk estimates from the quantitative risk assessment. At the same time, as stated in section II.C.3.c below, he finds those estimates to be roughly consistent with and generally supportive of the estimates from the evidence-based framework.

c. Conclusions on Level

Having carefully considered the public comments on the appropriate level of the Pb standard, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of Pb reached in the Criteria Document and Staff Paper, briefly summarized above in sections II.A.1 and II.A.2 and discussed more fully in sections II.A and II.B of the proposal, remain valid. In considering the level at which the primary Pb standard should be set, as in reaching a final decision on the need for revision of the current standard, the Administrator considers the entire body of evidence and information, in an integrated fashion, giving appropriate weight to each part of that body of evidence and information. In that context the Administrator continues to place primary consideration on the body of scientific evidence available in this review on the health effects associated with Pb exposure. In so doing, the Administrator primarily focuses on the air-related IQ loss evidence-based framework summarized in section II.C.3.a above and described in the proposal, recognizing that it provides useful guidance for making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary.

As described in section II.E.3.d of the proposal and recognized in section II.C.3.a above, the air-related IQ loss framework is used to inform the selection of a standard level that would protect against air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in subpopulations of children exposed to the level of the standard, taking into consideration uncertainties inherent in such estimates. This framework calls for identifying a target degree of protection in terms of an air-related IQ loss for such subpopulations of children (discussed further below), as well as two other parameters also relevant to this framework—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio.

With regard to estimates for air-to-blood ratio, the Administrator has further considered the evidence regarding air-to-blood relationships described in section II.A.2.a.iii above in light of advice from CASAC and comments from the public as described in section II.C.2.b above. Accordingly, he recognizes that the evidence includes support for ratios greater than 1:7 (the upper end of the range focused on in the proposal), including estimates ranging from 1:8 to 1:10. He also recognizes that the estimates developed from the quantitative exposure and risk assessments also include values greater than 1:7, including values ranging up to 1:10 and some higher. Additionally, as noted in section II.A.2.a.iii above, the evidence as a whole also indicates that variation in the value of the ratios appears to relate to the extent to which the range of air-related pathways are included and the magnitude of the air and blood Pb levels assessed, such that higher ratios appear to be associated with more complete assessments of air-related pathways and lower air and blood Pb levels. Taking all of these considerations into account, the Administrator concludes that the reasonable range of air-to-blood estimates to use in the air-related IQ loss framework includes ratios of 1:5 up to ratios on the order of 1:10. He does not consider lower ratios to be representative of the full range of air-related pathways and the ratios expected at today's air and blood Pb levels. The Administrator also concludes that it is appropriate to focus on 1:7 as a generally central value within this range.

With regard to C–R functions, the Administrator has further considered the evidence regarding quantitative relationships between IQ loss and blood Pb levels described in section II.A.2.c above, in light of advice from CASAC and comments from the public as described in section II.C.3.b above. He recognizes the evidence of nonlinearity and of steeper slopes at lower blood Pb levels (summarized in section II.A.2.c above), and as a result, he believes it is appropriate to focus on those analyses that are based on blood Pb levels that most closely reflect today's population of children in the U.S., recognizing that the evidence does not include analyses involving mean blood Pb levels as low as the mean blood Pb level for today's children. He notes that, as described in section II.C.3.b above, a review of the evidence with this focus in mind has identified four analyses that have a mean blood Pb level closest to today's mean for U.S. children and that yield four slopes ranging from −1.56 to −2.94, with a median of −1.75 IQ points per μg/dL (Table 3). The Administrator concludes that it is appropriate to consider this set of C–R functions for use in the air-related IQ loss evidence based framework, as this set of C–R functions best represents the evidence pertinent to children in the U.S. today. In addition, the Administrator determines that it is appropriate to give more weight to the central estimate for this set of functions, which is the median of the set of functions, and not to rely on any one function.

As noted in the proposal, in considering this evidence-based framework, the Administrator recognizes that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to protect against risk of neurocognitive effects in sensitive populations, such as IQ loss in children. With regard to making a public health policy judgment as to the appropriate protection against risk of air-related IQ loss and related effects, the Administrator believes that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognizes, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety.

The Administrator generally agrees with CASAC and the commenters who emphasize that the NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population. However, as discussed above in section II.C.3.b, it is important to note that in selecting a target degree of public health protection that should be afforded to at-risk populations of children in terms of air-related IQ loss as estimated by the evidence-based framework being applied in this review, the Administrator is not determining a specific quantitative public health policy goal for air-related IQ loss that would be acceptable or unacceptable for the entire population of children in the United States. Instead, he is determining what magnitude of estimated air-related IQ loss should be used in conjunction with this specific framework, in light of the uncertainties in the framework and the limitations in using the framework.

In that context, the air-related IQ loss framework provides estimates for the mean air-related IQ loss of a subset of the population of U.S. children, and there are uncertainties associated with those estimates. It provides estimates for that subset of children likely to be exposed to the level of the standard, which is generally expected to be the subpopulation of children living near sources who are likely to be most highly exposed. In providing estimates of the mean air-related IQ loss for this subpopulation of children, the framework does not provide estimates of the mean air-related IQ loss for all U.S. children. The Administrator recognizes, as discussed above, that EPA is unable to quantify the percentile of the U.S. population of children that corresponds to the mean of this sensitive subpopulation, nor can EPA confidently develop quantified estimates for upper percentiles for this subpopulation. EPA expects that the mean of this subpopulation represents a high, but not quantifiable, percentile of the U.S. population of children. As a result, the Administrator expects that a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children.[83]

In addition, EPA expects that the selection of a maximum, not to be exceeded, form in conjunction with a rolling 3-month averaging time over a three-year span, discussed in section II.C.2. above, will have the effect that the at-risk subpopulation of children will be exposed below the level of the standard most of the time. In light of this and the significant uncertainty in the relationship between time period of ambient level, exposure, and occurrence of a health effect, the choice of an air-related IQ loss to focus on in applying the framework should not be seen as a decision that a specific level of air-related IQ loss will occur in fact in areas where the revised standard is just met or that such a loss has been determined as acceptable if it were to occur. Instead, the choice of such an air-related IQ loss is one of the judgments that need to be made in using the evidence-based framework to provide useful guidance in making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary, taking into consideration the patterns of air quality that would likely occur upon just meeting the standard as revised in this rulemaking.

In considering the appropriate air-related IQ loss to accompany application of the framework, the Administrator has considered the advice of CASAC and public comments on this issue, discussed above in section II.C.3.b. The Administrator recognizes that comments on the proposal have highlighted the ambiguity in using an air-related IQ loss for the framework that is phrased in terms of a range. For example, if a range of 1–2 points IQ loss is selected, it is unclear whether the intent is to limit points of air-related IQ loss to below 1, below 2, or below some level in between. For clarity, it is more useful to use a specific level as compared to a range. In addition, recognizing the uncertainties inherent in evaluating the health impact of an IQ loss across a population, as well as the uncertainties in the inputs to the framework, the Administrator believes it is appropriate to use a whole number for the air-related IQ loss level.

In consideration of comments from CASAC and the public and in recognition of the uncertainties in the health effects evidence and related information, as well as the role of a selected air-related IQ loss in the application of the framework, the Administrator concludes that an air-related IQ loss of 2 points should be used in conjunction with the evidence-based framework in selecting an appropriate level for the standard. Given the uncertainties in the inputs to the framework, the uncertainties in the relationship between ambient levels, exposure period, and occurrence of health effects, and the focus of the framework on the sensitive subpopulation of more highly exposed children, a standard level selected using this air-related IQ loss, in combination with the selected averaging time and form, would significantly reduce and limit for a high percentage of U.S. children the risk of experiencing an air-related IQ loss of that magnitude.

With this specific air-related IQ loss in mind, the Administrator considered the application of this framework to a broad range of standard levels, using estimates for the two key parameters—air-to-blood ratio and C–R function—that are appropriate for use within the framework, as shown in Table 4 below. In so doing, the Administrator recognized that, relying on the median of the four C–R functions from analyses with blood Pb levels closest to those of today's children, a standard level in the lower half of the proposed range (0.10–0.20 μg/m^3) would limit the estimated mean IQ loss from air-related Pb to below 2 points, depending on the choice of air-to-blood ratio within the range from 1:5 to 1:10.

As noted above, however, the Administrator does not believe it is appropriate to consider only a single air-to-blood ratio. Using the air-to-blood ratio of 1:7, a generally central estimate within the well supported range of estimates, the estimates of air-related IQ loss are below a 2-point IQ loss for standard levels of 0.15 μg/m^3 and lower. At a level of 0.15 μg/m^3, the Administrator recognizes that use of a 1:10 ratio produces an estimate greater than 2 IQ points and use of a 1:5 ratio produces a lower IQ loss estimate. Given the uncertainties and limitations in the air-related IQ loss framework, the Administrator views it as appropriate to place primary weight on the results from this central estimate rather than estimates derived using air-to-blood-ratios either higher or lower than this ratio.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD

Potential level for standard (μg/m^3)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C–R functions with blood Pb levels closer to those of today's U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.50	>5 *	>5 *	4.4 (3.9–7.4)

[83] Further, in determining what level of estimated IQ loss should be used for evaluating the results obtained from this specific evidence-based framework, the Administrator is not determining that such an IQ loss is appropriate for use in other contexts.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD—Continued

Potential level for standard (μg/m³)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C–R functions with blood Pb levels closer to those of today's U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.40		4.9 (4.4–8.2)	3.5 (3.1–5.9)
0.30	5.3 (4.7–8.8)	3.7 (3.3–6.2)	2.6 (2.3–4.4)
0.25	4.4 (3.9–7.4)	3.1 (2.7–5.1)	2.2 (2.0–3.7)
0.20	3.5 (3.1–5.9)	2.5 (2.2–4.1)	1.8 (1.6–2.9)
0.15	2.6 (2.3–4.4)	1.8 (1.6–3.1)	1.3 (1.2–2.2)
0.10	1.8 (1.6–2.9)	1.2 (1.1–2.1)	0.9 (0.8–1.5)
0.05	0.9 (0.8–1.5)	0.6 (0.5–1.0)	0.4 (0.4–0.7)
0.02	0.4 (0.3–0.6)	0.2 (0.2–0.4)	0.2 (0.2–0.3)

* For these combinations of standard levels and air-to-blood ratios, the appropriateness of the C–R function applied in this table becomes increasingly uncertain such that no greater precision than ">5" for the IQ loss estimate is warranted.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of risk of air-related IQ loss. The Administrator finds that these quantitative assessments provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as summarized in section II.A.3 above and discussed in sections II.C and II.E.3.b of the proposal, for purposes of evaluating potential standard levels, the Administrator places less weight on the risk estimates than on the evidence-based assessment. Nonetheless, the Administrator finds that the risk estimates are roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates summarized above.[84]

In the Administrator's view, the above considerations, taken together, provide no evidence-or risk-based bright line that indicates a single appropriate level. Instead, there is a collection of scientific evidence and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making the public health policy judgment to select the appropriate standard level from a range of reasonable values. In addition, the results of the evidence-based framework are seen as a useful guide in determining whether the risks to public health from exposure to ambient levels of Pb in the air, in the context of a specified averaging time and form, provide a degree of protection from risk with an adequate margin of safety that is sufficient but not more than necessary.

Based on consideration of the entire body of evidence and information available at this time, as well as the recommendations of CASAC and public comments, the Administrator has decided that a level for the primary Pb standard of 0.15 μg/m³, in combination with the specified choice of indicator, averaging time, and form, is requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. The Administrator notes that this level is within the range recommended by CASAC, the Staff Paper, and by the vast majority of commenters. The Administrator concludes that a standard with a level of 0.15 μg/m³ will reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and the potential for cardiovascular and renal effects in adults.

The Administrator notes that the evidence-based framework indicates that for standard levels above 0.15 μg/m³, the estimated mean air-related IQ loss in the subpopulation of children exposed at the level of the standard would range in almost all cases from above 2 points to 5 points or more with the range of air-to-blood ratios considered. He concludes, in light of his consideration of all of the evidence, including the framework discussed above, that the protection from air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.15 μg/m³ would not be sufficient to protect public health with an adequate margin of safety.

In addition, the Administrator notes that for standard levels below 0.15 μg/m³, the estimated mean IQ loss from air-related Pb in the subpopulation of children exposed at the level of the standard would generally be somewhat to well below 2 IQ points regardless of which air-to-blood ratio within the range of ratios considered was used. The Administrator concludes in light of all of the evidence, including the evidence-based framework, that the degree of public health protection that standards below 0.15 μg/m³ would likely afford would be greater than what is necessary to protect public health with an adequate margin of safety.

The Administrator also recognizes that several commenters expressed concern that the proposal did not adequately address the need for the standard to be set with an adequate margin of safety. As noted above, in section I, the requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in

[84] For example, in considering a standard level of 0.2 μg/m³, we note that the risk assessment provides estimates falling within the range of 1.2 to 3.2 points IQ loss for the general urban case study and <3.7 for the primary Pb smelter subarea. These estimates are inclusive of the range of estimates for the 0.20 standard level presented in Table 4 based on the median C–R slope applied in the air-related IQ loss framework. As noted in section II.A.3.a above, these case studies, based on the nature of the population exposures represented by them, relate more closely to the air-related IQ loss evidence-based framework than other case studies assessed.

selecting a primary standard that includes an adequate margin of safety, the Administrator is seeking not only to prevent pollutant levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

Nothing in the Clean Air Act, however, requires the Administrator to identify a primary standard that would be protective against demonstrated harms, and then identify an additional ''margin of safety'' which results in further lowering of the standard. Rather, the Administrator's past practice has been to take margin of safety considerations into account in making decisions about setting the primary standard, including in determining its level, averaging time, form and indicator, recognizing that protection with an adequate margin of safety needs to be sufficient but not more than necessary.

Consistent with past practice, the Administrator has taken the need to provide for an adequate margin of safety into account as an integral part of his decision-making on the appropriate level, averaging time, form, and indicator of the standard. As discussed above, the consideration of health effects caused by different ambient air concentrations of Pb is extremely complex and necessarily involves judgments about uncertainties with regard to the relationships between air concentrations, exposures, and health effects. In light of these uncertainties, the Administrator has taken into account the need for an adequate margin of safety in making decisions on each of the elements of the standards. Consideration of the need for an adequate margin of safety is reflected in the following elements: selection of TSP as the indicator and the rejection of the use of PM_{10} scaling factors; selection of a maximum, not to be exceeded form, in conjunction with a 3-month averaging time that employs a rolling average, with the requirement that each month in the 3-month period be weighted equally (rather than being averaged by individual data) and that a 3-year span be used for comparison to the standard; and, the use of a range of inputs for the evidence-based framework, that includes a focus on higher air-to-blood ratios than the lowest ratio considered to be supportable, and steeper rather than shallower C-R functions, and the consideration of these inputs in selection of 0.15 $\mu g/m^3$ as the level of the standard. The Administrator concludes based on his review of all of the evidence (including the evidence-based framework) that when taken as a whole the standard selected today, including the indicator, averaging time, form, and level, will be sufficient but not more than necessary to protect public health, including the health of sensitive subpopulations, with an adequate margin of safety.

Thus, after carefully taking the above comments and considerations into account, and fully considering the scientific and policy views of the CASAC, the Administrator has decided to revise the level of the primary Pb standard to 0.15 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level and using the specified indicator, averaging time, and form would be requisite to protect public health with an adequate margin of safety. The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral and neurocognitive effects, in children. A standard set at this level provides a very significant increase in protection compared to the current standard. The Administrator believes that a standard set at 0.15 $\mu g/m^3$ would be sufficient to protect public health with an adequate margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

D. Final Decision on the Primary Lead Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and the public comments, the Administrator is revising the various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects. Specifically, the Administrator has decided to revise the level of the primary standard to a level of 0.15 $\mu g/m^3$, in conjunction with retaining the current indicator of Pb-TSP. The Administrator has also decided to revise the form and averaging time of the standard to a maximum (not to be exceeded) rolling 3-month average evaluated over a 3-year period.

Corresponding revisions to data handling conventions, including allowance for the use of Pb-PM_{10} data in certain circumstances, and the treatment of exceptional events are specified in revisions to Appendix R, as discussed in section IV below. Corresponding revisions to aspects of the ambient air monitoring and reporting requirements for Pb are discussed in section V below, including sampling and analysis methods (e.g., a new Federal reference method for monitoring Pb in PM_{10}, quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

III. Secondary Lead Standard

A. Introduction

The NAAQS provisions of the Act require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that secondary standards be set to eliminate all risk of adverse welfare effects, but rather at a level requisite to protect public welfare from those effects that are judged by the Administrator to be adverse.

This section presents the rationale for the Administrator's final decision to revise the existing secondary NAAQS. In considering the currently available evidence on Pb-related welfare effects, there is much information linking Pb to potentially adverse effects on organisms and ecosystems. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient Pb, the Administrator concludes that the available evidence supports revising the secondary standard but does not provide a sufficient basis for establishing a secondary standard for Pb that is different from the primary standard.

1. Overview of Welfare Effects Evidence

A secondary NAAQS addresses welfare effects and ''effects on welfare'' include, but are not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being. CAA section 302(h). A qualitative assessment of welfare effects evidence related to ambient Pb is summarized in this section, drawing from the Criteria Document, Chapter 6 of the Staff Paper and from the Proposed Rule. The presentation here summarizes several key aspects of the welfare evidence for Pb. Lead is persistent in the environment and accumulates in soils, aquatic systems (including sediments), and some biological tissues of plants, animals and other organisms, thereby providing long-term, multi-pathway exposures to organisms and ecosystems. Additionally, EPA recognizes that there have been a number of uses of Pb, especially as an ingredient in automobile fuel but also in other products such as paint, lead-acid batteries, and some pesticides, which have significantly contributed to widespread increases in Pb concentrations in the environment, a portion of which remains today (e.g., CD, Chapters 2 and 3).

Ecosystems near smelters, mines and other industrial sources of Pb have demonstrated a wide variety of adverse effects including decreases in species diversity, loss of vegetation, changes to community composition, decreased growth of vegetation, and increased number of invasive species. These sources may have multiple pathways for discharging Pb to ecosystems, and apportioning effects between air-related pathways and other pathways (e.g., discharges to water) in such cases is difficult. Likewise, apportioning these effects between Pb and other stressors is complicated because these point sources also emit a wide variety of other heavy metals and sulfur dioxide which may cause toxic effects. There are no field studies which have investigated effects of Pb additions alone but some studies near large point sources of Pb have found significantly reduced species composition and altered community structures. While these effects are significant, they are spatially limited: The majority of contamination occurs within 20 to 50 km of the emission source (CD, section AX7.1.4.2).

By far, the majority of air-related Pb found in terrestrial ecosystems was deposited in the past during the use of Pb additives in gasoline. Many sites receiving Pb predominantly through such long-range transport of gasoline-derived small particles have accumulated large amounts of Pb in soils (CD, p. AX7–98). There is little evidence that terrestrial sites exposed as a result of this long range transport of Pb have experienced significant effects on ecosystem structure or function (CD, section AX7.1.4.2 and p. AX7–98). Strong complexation of Pb by soil organic matter may explain why few ecological effects have been observed (CD, p. AX7–98). Studies have shown decreasing levels of Pb in vegetation which seems to correlate with decreases in atmospheric deposition of Pb resulting from the removal of Pb additives to gasoline (CD, section AX 7.1.4.2).

Terrestrial ecosystems remain primarily sinks for Pb but amounts retained in various soil layers vary based on forest type, climate, and litter cycling (CD, section 7.1). Once in the soil, the migration and distribution of Pb is controlled by a multitude of factors including pH, precipitation, litter composition, and other factors which govern the rate at which Pb is bound to organic materials in the soil (CD, section 2.3.5).

Like most metals the solubility of Pb is increased at lower pH. However, the reduction of pH may in turn decrease the solubility of dissolved organic material (DOM). Given the close association between Pb mobility and complexation with DOM, a reduced pH does not necessarily lead to increased movement of Pb through terrestrial systems and into surface waters. In areas with moderately acidic soil (i.e., pH of 4.5 to 5.5) and abundant DOM, there is no appreciable increase in the movement of Pb into surface waters compared to those areas with neutral soils (i.e., pH of approximately 7.0). This appears to support the theory that the movement of Pb in soils is limited by the solubilization and transport of DOM. In sandy soils without abundant DOM, moderate acidification appears likely to increase outputs of Pb to surface waters (CD, section AX 7.1.4.1).

Lead exists in the environment in various forms which vary widely in their ability to cause adverse effects on ecosystems and organisms. Current levels of Pb in soil also vary widely depending on the source of Pb but in all ecosystems Pb concentrations exceed natural background levels. The deposition of gasoline-derived Pb into forest soils has produced a legacy of slow moving Pb that remains bound to organic materials despite the removal of Pb from most fuels and the resulting dramatic reductions in overall deposition rates. For areas influenced by point sources of air Pb, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms. Adverse effects associated with Pb include neurological, physiological and behavioral effects which may influence ecosystem structure and functioning. Ecological soil screening levels (Eco-SSLs) have been developed for Superfund site characterizations to indicate concentrations of Pb in soils below which no adverse effects are expected to plants, soil invertebrates, birds and mammals. Values like these may be used to identify areas in which there is the potential for adverse effects to any or all of these receptors based on current concentrations of Pb in soils.

Atmospheric Pb enters aquatic ecosystems primarily through the erosion and runoff of soils containing Pb and deposition (wet and dry). While overall deposition rates of atmospheric Pb have decreased dramatically since the removal of Pb additives from gasoline, Pb continues to accumulate and may be re-exposed in sediments and water bodies throughout the United States (CD, section 2.3.6).

Several physical and chemical factors govern the fate and bioavailability of Pb in aquatic systems. A significant portion of Pb remains bound to suspended particulate matter in the water column and eventually settles into the substrate. Species, pH, salinity, temperature, turbulence and other factors govern the bioavailability of Pb in surface waters (CD, section 7.2.2).

Lead exists in the aquatic environment in various forms and under various chemical and physical parameters which determine the ability of Pb to cause adverse effects either from dissolved Pb in the water column or Pb in sediment. Current levels of Pb in water and sediment also vary widely depending on the source of Pb. Conditions exist in which adverse effects to organisms and thereby ecosystems may be anticipated given experimental results. It is unlikely that dissolved Pb in surface water constitutes a threat to ecosystems that are not directly influenced by point sources. For Pb in sediment, the evidence is less clear. It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The long residence time of Pb in sediment and its ability to be

resuspended by turbulence make Pb likely to be a factor for the foreseeable future. Criteria have been developed to indicate concentrations of Pb in water and sediment below which no adverse effects are expected to aquatic organisms. These values may be used to identify areas in which there is the potential for adverse effects to receptors based on current concentrations of Pb in water and sediment.

2. Overview of Screening Level Ecological Risk Assessment

This section presents a brief summary of the screening-level ecological risk assessment conducted by EPA for this review. The assessment is described in detail in *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas, Pilot Phase* (ICF, 2006). Various limitations have precluded performance of a full-scale ecological risk assessment. The discussion here is focused on the screening level assessment performed in the pilot phase (ICF, 2006) and takes into consideration CASAC recommendations with regard to interpretation of this assessment (Henderson, 2007a, b). The following summary focuses on key features of the approach used in the assessment and presents only a brief summary of the results of the assessment.

A screening level risk assessment was performed to estimate the potential for ecological risks associated with exposures to Pb emitted into ambient air. A case study approach was used which included areas surrounding a primary Pb smelter and a secondary Pb smelter, as well as a location near a nonurban roadway. Soil, surface water, and/or sediment concentrations were estimated for each of the three initial case studies from available monitoring data or modeling analysis, and then compared to ecological screening benchmarks to assess the potential for ecological impacts from Pb that was emitted into the air. A national-scale screening assessment was also used to evaluate surface water and sediment monitoring locations across the United States for the potential for ecological impacts associated with atmospheric deposition of Pb. An additional case study was identified to look at gasoline derived Pb effects on an ecologically vulnerable ecosystem but various limitations precluded any analyses.

The ecological screening values used in this assessment to estimate the potential for ecological risk were developed from the Eco-SSLs methodology, EPA's recommended ambient water quality criteria, and sediment screening values developed by MacDonald and others (2000, 2003). Soil screening values were derived for this assessment using the Eco-SSL methodology with the toxicity reference values for Pb (USEPA, 2005d, 2005e) and consideration of the inputs on diet composition, food intake rates, incidental soil ingestion, and contaminant uptake by prey (details are presented in section 7.1.3.1 and Appendix L, of ICF, 2006). Hardness specific surface water screening values were calculated for each site based on EPA's recommended ambient water quality criteria for Pb (USEPA, 1984). For sediment screening values, the assessment relied on sediment ''threshold effect concentrations'' and ''probable effect concentrations'' developed by MacDonald et al. (2000). The methodology for these sediment criteria is described fully in section 7.1.3.3 and Appendix M of the pilot phase Risk Assessment Report (ICF, 2006).

A Hazard Quotient (HQ) was calculated for various receptors to determine the potential for risk to that receptor. The HQ is calculated as the ratio of the media concentration to the ecotoxicity screening value, and represented by the following equation:

HQ = (estimated Pb media concentration) ÷ (ecotoxicity screening value)

For each case study, HQ values were calculated for each location where either modeled or measured media concentrations were available. Separate soil HQ values were calculated for each ecological receptor group for which an ecotoxicity screening value has been developed (i.e., birds, mammals, soil invertebrates, and plants). HQ values less than 1.0 suggest that Pb concentrations in a specific medium are unlikely to pose significant risks to ecological receptors. HQ values greater than 1.0 indicate that the expected exposure exceeds the ecotoxicity screening value and that there is a potential for adverse effects.

There are several uncertainties that apply across case studies noted below:

- The ecological risk screen is limited to specific case study locations and other locations for which Pb data were available. Efforts were made to ensure that the Pb exposures assessed were attributable to airborne Pb and not dominated by nonair sources. However, there is uncertainty as to whether other sources might have actually contributed to the Pb exposure estimates.
- A limitation to using the selected ecotoxicity screening values is that they might not be sufficient to identify risks to some threatened or endangered species or unusually sensitive aquatic ecosystems (e.g., CD, p. AX7–110).
- The methods and database from which the surface water screening values (i.e., the AWQC for Pb) were derived is somewhat dated. New data and approaches (e.g., use of pH as indicator of bioavailability) may now be available to estimated the aquatic toxicity of Pb (CD, sections X7.2.1.2 and AX7.2.1.3).
- No adjustments were made for sediment-specific characteristics that might affect the bioavailability of Pb in sediments in the derivation of the sediment quality criteria used for this ecological risk screen (CD, sections 7.2.1 and AX7.2.1.4; Appendix M, ICF, 2006). Similarly, characteristics of soils for the case study locations were not evaluated for measures of bioavailability.
- Although the screening value for birds used in this analysis is based on reasonable estimates for diet composition and assimilation efficiency parameters, it was based on a conservative estimate of the relative bioavailability of Pb in soil and natural diets compared with water soluble Pb added to an experimental pellet diet (Appendix L, ICF, 2006).

The following is a brief summary of key observations related to the results of the screening-level ecological risk assessment. A complete discussion of the results is provided in Chapter 6 of the Staff Paper and the complete presentation of the assessment and results is presented in the pilot phase Risk Assessment Report (ICF, 2006).

For the case studies, the concentrations of Pb in soil and sediments in various locations exceeded screening values for these media indicating potential for adverse effects to terrestrial organisms (plants, birds and mammals) and to sediment dwelling organisms. While it was not possible to dissect the contributions of air Pb emissions from other sources, it is likely that, at least for the primary smelter, that the air contribution is significant. For the other case studies, the contributions of current air emissions to the Pb burden, is less clear.

The national-scale screen of surface water data initially identified 15 areas for which water column levels of dissolved Pb were greater than hardness adjusted chronic criteria for the protection of aquatic life indicating a potential for adverse effect if concentrations were persistent over chronic periods. Acute criteria were not exceeded at any of these locations. The extent to which air emissions of Pb have contributed to these surface water Pb concentrations is unclear. In the national-scale screen of sediment data associated with the 15 surface water sites described above, threshold effect

concentration-based HQs at nine of these sites exceeded 1.0. Additionally, HQs based on probable effect concentrations exceeded 1.0 at five of the sites, indicating probable adverse effects to sediment dwelling organisms. Thus, sediment Pb concentrations at some sites are high enough that there is a likelihood that they would cause adverse effects to sediment dwelling organisms. However, the contribution of air emissions to these concentrations is unknown.

B. Conclusions on the Secondary Lead Standard

1. Basis for the Proposed Decision

The current standard was set in 1978 to be identical to the primary standard (1.5 μg Pb/m^3, as a maximum arithmetic mean averaged over a calendar quarter), the basis for which is summarized in section II.C.1. At the time the standard was set, the Agency concluded that the primary air quality standard would adequately protect against known and anticipated adverse effects on public welfare, as the Agency stated that it did not have evidence that a more restrictive secondary standard was justified. In the rationale for this conclusion, the Agency stated that the available evidence cited in the 1977 Criteria Document indicated that ''animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans'' (43 FR 46256). The Agency recognized that Pb may be deposited on the leaves of plants and present a hazard to grazing animals. With regard to plants, the Agency stated that Pb is absorbed but not accumulated to any great extent by plants from soil, and that although some plants may be susceptible to Pb, it is generally in a form that is largely unavailable to them. Further the Agency stated that there was no evidence indicating that ambient levels of Pb result in significant damage to manmade materials and Pb effects on visibility and climate are minimal.

The secondary standard was subsequently considered during the 1980s in development of the 1986 Criteria Document (USEPA, 1986a) and the 1990 Staff Paper (USEPA, 1990b). In summarizing OAQPS staff conclusions and recommendations at that time, the 1990 Staff Paper stated that a qualitative assessment of available field studies and animal toxicological data suggested that ''domestic animals and wildlife are as susceptible to the effects of lead as laboratory animals used to investigate human lead toxicity risks.'' Further, the 1990 Staff Paper highlighted concerns over potential ecosystem effects of Pb due to its persistence, but concluded that pending development of a stronger database that more accurately quantifies ecological effects of different Pb concentrations, consideration should be given to retaining a secondary standard at or below the level of the then-current secondary standard of 1.5 μg/m^3.

Given the full body of current evidence, despite wide variations in Pb concentrations in soils throughout the country, Pb concentrations are in excess of concentrations expected from geologic or other non-anthropogenic forces. There are several difficulties in quantifying the role of recent air emissions of Pb in the environment: Some Pb deposited before the standard was enacted is still present in soils and sediments; historic Pb from gasoline continues to move slowly through systems as does current Pb derived from both air and nonair sources. Additionally, the evidence of adversity in natural systems is limited due in no small part to the difficulty in determining the effects of confounding factors such as multiple metals or factors influencing bioavailability in field studies.

The evidence summarized above, in the Proposed Rule, in section 4.2 of the Staff Paper, and described in detail in the Criteria Document, informs our understanding of Pb in the environment today and evidence of environmental Pb exposures of potential concern. For areas influenced by point sources of air Pb that meet the current standard, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms (CD, sections 3.2 and AX7.1.2.3). In addition, conditions exist in which Pb associated adverse effects to aquatic organisms and thereby ecosystems may be anticipated given experimental results. While the evidence does not indicate that dissolved Pb in surface water constitutes a threat to those ecosystems that are not directly influenced by point sources, the evidence regarding Pb in sediment is less clear (CD, sections AX7.2.2.2.2 and AX7.2.4). It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The Staff Paper concluded, based on laboratory studies and current media concentrations in a wide range of areas, that it seems likely that adverse effects are occurring, particularly near point sources, under the current standard. The long residence time of Pb in sediment and its ability to be resuspended by turbulence make Pb contamination likely to be a factor for the foreseeable future. Based on this information, the Staff Paper concluded that the evidence suggests that the environmental levels of Pb occurring under the current standard, set nearly thirty years ago, may pose risk of adverse environmental effect.

In addition to the evidence-based considerations described in the previous section, the screening level ecological risk assessment is informative, taking into account key limitations and uncertainties associated with the analyses. As discussed in the previous section, as a result of its persistence, Pb emitted in the past remains today in aquatic and terrestrial ecosystems of the United States. Consideration of the environmental risks associated with the current standard is complicated by the environmental burden associated with air Pb concentrations that exceeded the current standard, predominantly in the past. Concentrations of Pb in soil and sediments associated with the case studies exceeded screening values for those media, indicating potential for adverse effect in terrestrial organisms (plants, birds, and mammals) and in sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources has not been quantified, air emissions from the primary smelting facility at least are substantial (Appendix D, USEPA 2007b; ICF 2006).

The national-scale screens, which are not focused on particular point source locations, indicate the ubiquitous nature of Pb in aquatic systems of the United States today. Further, the magnitude of surface water Pb concentrations in several aquatic systems exceeded screening values and sediment Pb concentrations at some sites in the national-scale screen were high enough that the likelihood that they would cause adverse effects to sediment dwelling organisms may be considered ''probable''. A complicating factor in interpreting the findings for the national-scale screening assessments is the lack of clear apportionment of Pb contributions from air as compared to nonair sources, such as industrial and municipal discharges. While the contribution of air emissions to the elevated concentrations has not been quantified, documentation of historical trends in the sediments of many water bodies has illustrated the sizeable contribution that airborne Pb can have on aquatic systems (e.g., Staff Paper, section 2.8.1). This documentation also indicates the greatly reduced contribution in many systems as compared to decades ago (presumably

reflecting the phase-out of Pb-additives from gasoline used by cars and trucks). However, the timeframe for removal of Pb from surface sediments into deeper sediment varies across systems, such that Pb remains available to biological organisms in some systems for much longer than in others (Staff Paper, section 2.8; CD, pp. AX7–141 to AX7–145).

The case study locations included in the screening assessment, with the exception of the primary Pb smelter site, are currently meeting the current Pb standard, yet Pb occurs in soil and aquatic sediment in some locations at concentrations indicative of a potential for harm to some terrestrial and sediment dwelling organisms. While the role of airborne Pb in determining these Pb concentrations is unclear, the historical evidence indicates that airborne Pb can create such concentrations in sediments and soil.

Based on its review of the Staff Paper, CASAC advised the Administrator that ''*The Lead Panel unanimously affirms its earlier judgments that, as with the primary (public-health based) Lead NAAQS, the secondary (public-welfare based) standard for lead also needs to be substantially lowered * * **'' Therefore at a minimum, the level of the secondary Lead NAAQS should be at least as low as the level of the recommended primary lead standard.'' (Henderson, 2008a). CASAC also recognized that EPA lacked data to provide a clear quantitative basis for setting a secondary standard that differed from the primary standard. (Henderson 2007a, 2008a).

In considering the adequacy of the current standard in providing protection from Pb-related adverse effects on public welfare, the Administrator considered in the proposal the body of available evidence (briefly summarized above in section III.). The proposal indicated that depending on the interpretation, the available data and evidence, primarily qualitative, suggests that there was the potential for adverse environmental impacts under the current standard. Given the limited data on Pb effects in ecosystems, it is necessary to look at evidence of Pb effects on organisms and extrapolate to ecosystem effects. Therefore, taking into account the available evidence and current media concentrations in a wide range of areas, the Administrator concluded in the proposal that there is potential for adverse effects occurring under the current standard, although there are insufficient data to provide a quantitative basis for setting a secondary standard different than the primary. While the role of current airborne emissions is difficult to apportion, deposition of Pb from air sources is occurring and this ambient Pb is likely to be persistent in the environment similarly to that of historically deposited Pb which has persisted, although location specific dynamics of Pb in soil result in differences in the timeframe during which Pb is retained in surface soils or sediments where it may be available to ecological receptors (USEPA, 2007b, section 2.3.3).

Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposed to revise the current secondary Pb standard by making it identical in all respects to the proposed primary Pb standard (described in section II.D above).

2. Comments on the Proposed Secondary Standard

EPA notes that CASAC, in their July 2008 letter, did not provide comments on the discussion and proposal regarding the secondary standard. Commenters who expressed an opinion on the proposed revision to the secondary standard, including a number of national organizations, individual States, Tribal associations, and local organizations, and combined comments from various environmental groups supported the position that the secondary Pb standard should be revised to the level of the primary standard. Some commenters recommended that the secondary standard be no less stringent than the primary, one commenter recommended that the standard be no more stringent than the primary, and some commenters recommended that the secondary standard be identical to the primary. One commenter concurred with the Agency's finding, consistent with CASAC's prior advice, that the current scientific knowledge was lacking and that further research was necessary to quantitatively inform an appropriate secondary standard. For the reasons discussed above and in the proposal, we agree with commenters that the secondary standard should be at this time set equal to the primary in indicator, level, form and averaging time and that more research is needed to further inform the development of a secondary Pb standard.

3. Administrator's Conclusions

In considering the adequacy of the current secondary standard in providing requisite protection from Pb-related adverse effects on public welfare, the Administrator has considered the body of available evidence (briefly summarized above and in the proposal). The screening-level risk assessment, while limited and accompanied by various uncertainties, suggests occurrences of environmental Pb concentrations existing under the current standard that could have adverse environmental effects in terrestrial organisms (plants, birds and mammals) and in sediment dwelling organisms. Environmental Pb levels today are associated with atmospheric Pb concentrations and deposition that have combined with a large reservoir of historically deposited Pb in environmental media.

In considering this evidence, as well as the views of CASAC, summarized above, the Staff Paper and associated support documents, and views of public commenters on the adequacy of the current standard, the Administrator concurs with CASAC's recommendation that the secondary standard should be substantially revised and concludes that given the current state of evidence, the current secondary standard for Pb is not requisite to protect public welfare from known or anticipated adverse effects.

C. Final Decision on the Secondary Lead Standard

The secondary standard is defined in terms of four basic elements: Indicator, averaging time, level and form, which serve to define the standard and must be considered collectively in evaluating the welfare protection afforded by the standards. With regard to the pollutant indicator for use in a secondary NAAQS, EPA notes that Pb is a persistent pollutant to which ecological receptors are exposed via multiple pathways. While the evidence indicates that the environmental mobility and ecological toxicity of Pb are affected by various characteristics of its chemical form, and the media in which it occurs, information is insufficient to identify an indicator other than total Pb that would provide protection against adverse environmental effect in all ecosystems nationally. Thus, the same rationale for retaining Pb-TSP for the indicator apply here as for the primary standard.

Lead is a cumulative pollutant with environmental effects that can last many decades. There is a general lack of data that would indicate the appropriate level of Pb in environmental media that may be associated with adverse effects. The EPA notes the influence of airborne Pb on Pb in aquatic systems and of changes in airborne Pb on aquatic systems, as demonstrated by historical patterns in sediment cores from lakes and Pb measurements (section 2.8.1; CD, section AX7.2.2; Yohn *et al.*, 2004; Boyle *et al.*, 2005), as well as the

comments of the CASAC Pb panel that a significant change to current air concentrations (e.g., via a significant change to the standard) is likely to have significant beneficial effects on the magnitude of Pb exposures in the environment and Pb toxicity impacts on natural and managed terrestrial and aquatic ecosystems in various regions of the U.S., the Great Lakes and also U.S. territorial waters of the Atlantic Ocean (Henderson, 2007a, Appendix E). The Administrator concurs with CASAC's conclusion that the level of the secondary standard should be set at least as low as the level of the primary standard and that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level, or form. Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator is revising the current secondary Pb standard by making it identical in all respects to the primary Pb standard.

IV. Appendix R—Interpretation of the NAAQS for Lead

EPA proposed to add Appendix R, Interpretation of the National Ambient Air Quality Standards for Pb, to 40 CFR part 50 in order to provide data handling procedures for the proposed Pb standard. The proposed Appendix R detailed the computations necessary for determining when the proposed Pb NAAQS would be met. The proposed appendix also addressed data reporting; sampling frequency and data completeness considerations; the use of scaled low-volume Pb-PM_{10} data as a surrogate for Pb-TSP data (or vice versa), including associated scaling instructions; and rounding conventions. The purpose of a data interpretation guideline in general is to provide the practical details on how to make a comparison between multi-day, possibly multi-monitor, and (in the unique instance of the proposed Pb NAAQS) possibly multi-parameter (i.e., Pb-TSP and/or low-volume Pb-PM_{10}) ambient air concentration data to the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. When data are insufficient, for example because of failure to collect valid ambient data on enough days in enough months (because of operator error or events beyond the control of the operator), no determination of current compliance or violation is possible.

In the proposal, proposed rule text was provided only for the example of a Pb NAAQS based on a Pb-TSP indicator, a monthly averaging time, and a second maximum form. The preamble discussed how the rule text would be different to accommodate a Pb-PM_{10} indicator and/or a quarterly averaging time with a not-to-be-exceeded form.

A. Ambient Data Requirements

1. Proposed Provisions

Section 3 of the proposed Appendix R, Requirements for Data Used for Comparisons with the Pb NAAQS and Data Reporting Considerations, specified that all valid FRM/FEM Pb-TSP data and all valid FRM/FEM Pb-PM_{10} data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting specified monitoring requirements in 40 CFR part 58 related to quality assurance, monitoring methods, and monitor siting shall be used in design value calculations.[85] Because 40 CFR 58 requirements were revised in 2006 and were proposed for further revision in this rulemaking, and because the FRM/FEM criteria for Pb-PM_{10} are being established for the first time in this rulemaking, EPA wanted to provide clarity about whether data collected before the effective dates of the 2006 revisions and of this final rule could be used for comparisons to the NAAQS. The proposal therefore provided that Pb-TSP and Pb-PM_{10} data representing sample collection periods prior to January 1, 2009 (i.e., ''pre-rule'' data) would also be considered valid for NAAQS comparisons and related attainment/nonattainment determinations if the sampling and analysis methods that were utilized to collect those data were consistent with the provisions of 40 CFR part 58 that were in effect at the time of original sampling or that are in effect at the time of the attainment/nonattainment determination, and if such data are submitted to AQS prior to September 1, 2009.

This section of the proposed rule also required that in the future Pb data be reported in terms of local temperature and pressure conditions, but provided that Pb data collected prior to January 1, 2009 and reported to AQS in terms of standard temperature and pressure conditions would be compared directly to the level of the NAAQS without re-adjustment to local conditions, unless the monitoring agency voluntarily re-submitted them with such adjustment.

Finally, this section provided for the taking of make-up samples within seven days after a scheduled sampling day fails to produce valid data. It also specified that all data, including scheduled samples, make-up samples, and any extra samples (i.e., non-scheduled samples that are not eligible to be considered make-up samples because they either were taken too long after the missed sample or another non-scheduled sample is already being used as the make-up sample) would be used in calculating the monthly average concentration.

2. Comments on Ambient Data Requirements

One commenter argued that Pb concentrations should continue, as in the past, to be reported in terms of standard temperature and pressure conditions and that only those values should be compared to the level of the NAAQS. In support of this view, this commenter claimed generally that ambient air Pb concentrations used in deriving relationships between air Pb concentrations and blood Pb levels were in terms of standard temperature and pressure. Another commenter expressed a similar but less specific concern about consistency between the conditions for reporting concentrations and the logic used by the Administrator to set the level of the NAAQS. For reasons described in the Response to Comments document, EPA rejects these arguments.

Another commenter supported the requirement for Pb concentrations to be submitted in terms of local conditions and the option of monitoring agencies to resubmit older data in those terms, but wanted EPA to restrain monitoring agencies which do resubmit data from withdrawing the data submitted earlier in terms of standard conditions. EPA agrees that the previously submitted data should not be withdrawn, but we will instruct states to this effect through guidance rather than by regulation, since nowhere now do the air monitoring or data interpretation regulations address the possibility of data withdrawal.

As proposed, 40 CFR 50.3 is amended to say that Pb-TSP concentrations are to be reported in terms of local conditions of temperature and pressure. The corresponding requirement for Pb-PM_{10} data is contained in the FRM method specification in Appendix Q. Appendix R retains a statement that this is the manner in which both types of data are submitted.

[85] As explained below, under the proposal sufficiently complete Pb-TSP data would take precedence over Pb-PM_{10} data, so not all Pb-PM_{10} data would necessarily be actually used in the design value calculations.

3. Conclusions on Ambient Data Requirements

The final provisions of Appendix R regarding what ambient data are to be used for comparisons to the NAAQS are as proposed. Sections IV.C and IV.D of this preamble also address certain related issues involving what ambient data are to be used in making comparisons to the NAAQS.

B. Averaging Time and Procedure

1. Proposal on Averaging Time and Procedure

EPA proposed in the alternative two averaging times for the revised NAAQS: A monthly period and a calendar quarter. In both approaches, the averaging time would be based on non-overlapping periods, the 12 individual calendar months in the case of a monthly averaging time and the 4 conventional calendar quarters (January–March, etc.) in the case of calendar quarter. In the case of a monthly averaging time all valid 24-hour Pb concentration data from the month would be arithmetically averaged to calculate the average concentration, and the average would be considered valid depending on the completeness of the data relative to the monitoring schedule, see section IV.C. Similarly, in the case of a quarterly average, all valid 24-hour data would be averaged to calculate the quarterly average concentration.

2. Comments on Averaging Time and Procedure

There were many public comments on the selection of the averaging time, addressed in section II.C.2. For the reasons discussed in that section, the final rule establishes the averaging time as a rolling 3-month period. Also, the final rule contains a 2-step procedure for calculating the 3-month average concentration, in which the average concentration for individual calendar months are calculated from all available valid 24-hour data in each month, and then three adjacent monthly averages are summed and divided by three to form the 3-month average concentration. In this way, each month's average will be weighted the same in calculating the 3-month average even if the months have different numbers of days with valid 24-hour concentration data. As explained in section II.C.2, this reduces the possibility that any one month's concentration could be very high compared to the 3-month average, compared to the proposed 1-step approach to calculating an average over three months.

3. Conclusions on Averaging Time and Procedure

The final rule establishes the averaging time as a rolling 3-month period. The final rule contains a 2-step procedure for calculating the average concentration for a 3-month period. First, the average concentration for individual calendar months are calculated from all available valid 24-hour data in each month giving equal weight to each day with valid monitoring data. Then, the three adjacent monthly averages are summed and divided by three to form the 3-month average concentration.[86]

The final text of Appendix R also includes a provision that gives the Administrator discretion to use an alternate 3-step approach to calculating the 3-month average concentration instead of the 2-step approach described above. The Administrator will have this discretion only in a situation in which the number of extra sampling days during a month within the 3-month period is greater than the number of successfully completed scheduled and make-up sample days in that month. In such a situation, including all the available valid sampling days in the calculation of a monthly average concentration (and thereby into the calculation of a 3-month average concentration) might in result in an unrepresentative value for the monthly average concentration. This provision is to protect the integrity of the monthly and 3-month average concentration values in situations in which, by intention or otherwise, extra sampling days are concentrated in a period or periods during which ambient concentrations are particularly high or low. As explained in section IV.C, the final version of Appendix R does not apply a completeness requirement to individual months, but instead applies the completeness criteria to each 3-month averaging period as a whole. As a result, it is conceivable that a month used to form a valid 3-month average may itself have as few as two scheduled sampling days with valid data if the other two months have valid data for all five scheduled sampling days. In such a case, even a small number of extra samples could dominate the monthly average, which would then in turn contribute to the 3-month average with a weighting of one-third. The extra sampling days, however, may systematically tend to have been higher or lower Pb concentration days.[87] For example, a monitoring agency might have deliberately increased sampling frequency during episodes of high Pb concentration in order to better understand the scope and causes of high concentrations. It is also possible for a monitoring agency to pick days for extra sampling in ways that make those days tend to have lower Pb concentrations, for example by paying attention to wind direction or source operations. If extra sampling days are systematically related to concentration, the average of all data during a month might not fairly represent the average of the daily concentrations actually occurring across all the days in the month. The potential for the monthly average to become seriously distorted increases as the number of extra sampling days increases. Therefore, the final rule does not trigger the discretion to use the alternate 3-step approach described below unless the number of extra sampling days is greater than the number of scheduled and make-up days that have valid data.

In the case of a Pb sampling schedule in which an ambient sample is scheduled to be taken every sixth day, the first step in the 3-step approach is to average all scheduled, make-up, and extra samples taken on a given scheduled sample day and on any of the five days following that sampling day. Typically, there will be up to five such 6-day averages in a month; there can be fewer 6-day averages if one or more of the 6-day periods yielded no valid data. The second step is to average these 6-day averages together to calculate the monthly average. This approach has the effect of giving equal weight to each 6-day period during a month regardless of how many samples were actually obtained during the 6 days, which mitigates the potential for the monthly average to be distorted. The third step in calculating the 3-month average would be to average the three monthly averages giving equal weight to each

[86] In the final Appendix R, there is a provision to calculate a ''3-month'' average based on only one (or two) months of data if two (or one) of the months in the 3-month period have no valid reported data at all. In this case, the sum of the available monthly averages is divided by the number of months contributing data. Because a lack of data for an entire month (or two) would mean that the completeness over a 3-month period cannot be higher than 67 percent (or 33 percent), which is less than the normal requirement for 75 percent completeness, a situation like this could result in a valid 3-month average concentration only via application of the ''above NAAQS'' diagnostic data substitution test described in section IV.C. With that test, if substituting historically low data for the month (or two months) of missing data still results in a 3-month average above the level of the NAAQS, then the 3-month mean computed from only two (or one) months of data is deemed valid and complete.

[87] The scheduled sampling days, in contrast, are expected to be uncorrelated with Pb concentration, since they do not emphasize any particular day of the week.

month, as described above in the standard 2-step approach to calculating the 3-month mean.

The above discussion has been simplified for easier understanding, by not addressing all the possible situations that can arise and that are addressed explicitly or implicitly by the final rule text. The following provides additional details.

(1) The example presumes a one-in-six sampling schedule, which is the minimum required in the final rule. If the site is operating on a one-in-three schedule, the first step in the alternate approach is to average the daily concentrations over periods of three days, then those three-day averages (up to 10, typically) are averaged to get the monthly average.

(2) The first day of scheduled one-in-six sampling typically will not fall on the first day of the calendar month, and there may be make-up or extra samples on the 1 to 5 days (1 or 2 days in the case of one-in-three sampling) of the same calendar month that precede the first scheduled day of the month. These samples will stay associated with their actual calendar month as follows. Any extra and make-up samples taken within the month but before the first scheduled sampling day of the month will be associated with and averaged with the last scheduled sampling day of the month and any days in the month following the last scheduled sampling day. In a 30-day month, this approach will always associate the last scheduled day of the month with five unscheduled days within the same month just as for the other scheduled sampling days, even when it is less than five days from the start of the next month, preserving the concept of giving equal weight to equal calendar time.

(3) In February, with 28 or 29 days, under the final rule's alternate approach one of the scheduled sampling days will end up associated with fewer than five unscheduled days, but those days will nevertheless carry equal weight with the four 6-day periods. EPA recognizes this slight departure from the concept of giving equal weight to equal calendar time.

(4) In months with 31 days, there will also be a departure from the concept of equal weight to equal calendar time. Most often, one of the ''6-day'' periods will actually have 7 days included in it. Rarely, the last day of a 31-day month will be a scheduled sampling day, and the effect will be to give the Pb measurement from this day equal weight in the monthly average as the five 6-day averages. In such a case, the Administrator may choose not to exercise the discretion to use the alternate 3-step approach, for example if the measurement on the last day of a 31-day month is unusually high or low.

C. Data Completeness

1. Proposed Provisions

EPA proposed that if a monthly averaging time were selected, the basic completeness requirement for a monthly average concentration to be valid would be that at least 75 percent of the scheduled sampling days have produced valid reported data. EPA also proposed that if the maximum quarterly average concentration were selected, each month in the quarter would be required to meet this completeness test. Two ''diagnostic'' tests involving data substitution were proposed, which in some cases would allow a reasonably confident conclusion about the existence of an exceedance or lack thereof to be made despite data completeness of less than 75 percent.

EPA also asked for comment, but did not propose any specifics for, two other tests that could allow conclusions about exceedances to be made in additional situations when data completeness was substandard. One of these would compare the average monthly concentration to an unspecified fraction of the level of the NAAQS, in effect applying a safety margin to offset the risk of error caused by the small sample size of measured concentrations. The other test would create a statistically derived confidence interval for the average monthly concentration based on the daily data and then would test whether that interval was entirely above (indicating an exceedance) or entirely below (indicating the lack of an exceedance) the level of the NAAQS. These same tests would be used under the alternative proposal of a quarterly averaging time. However, in the proposal, EPA described these completeness tests only in the context of a monthly average concentration (i.e., for the proposed second maximum monthly average form).

2. Comments on Data Completeness

No comments were received directly on the details of the proposal regarding data completeness. One commenter expressed concern that the two diagnostic tests for use when data are less than 75 percent complete could leave an indeterminate outcome even when the weight of evidence indicates an exceedance or a lack of an exceedance. EPA believes that a proposed provision of Appendix R, which is included in the final rule, allowing for case-by-case use of incomplete data with the approval of the Administrator allows EPA to appropriately address such a situation.

3. Conclusions on Data Completeness

The final rule differs from the monthly averaging time version of the proposal in the following aspects. These changes have been made to align Appendix R with the selected maximum rolling 3-month averaging time and form of the NAAQS and the final requirement for one-in-six day sampling (discussed in section V of this preamble). Because one-in-six sampling means that typically only five samples will be scheduled each month, only a single sample could be missed (and not made up) without completeness falling below the 75 percent level. Therefore, requiring 75 percent completeness at the monthly level could easily result in one month in a 3-year period being judged incomplete, making it impossible to make a finding of attainment of the NAAQS even when the available data in that and other months strongly suggest attainment.[88] To avoid this, the final rule applies the 75 percent completeness requirement at the 3-month level by averaging the three monthly completeness values to get the 3-month completeness value. Specifically, under the final rule 3-month completeness would be calculated and tested for every 3-month period. This reduces the likelihood of an incompleteness situation for an entire 3-year evaluation period due to as few as two missed samples in a single month.

In the proposed rule, the two diagnostic tests based on data substitution were applied within an individual month that has incomplete data relative to the 75 percent requirement. In the final rule, the tests remain and data are still substituted within the individual month (i.e., if a day of concentration data is missing from January in one of the three years, the missing concentration is substituted with the highest or lowest (depending on which diagnostic test is being applied) available measured Pb concentration from other days in the three Januarys). However, the last step of the diagnostic test, comparison of the substituted average concentration to the level of the NAAQS, is done for the 3-month average concentration not the monthly average concentration since a 3-month averaging time has been selected.

[88] Incomplete data for one month of a 3-year period would not necessarily prevent a finding of a NAAQS violation, because a single 3-month average concentration above the NAAQS level in any period not affected by that month's incompleteness would constitute a violation.

EPA is not finalizing any version of either of the two incompleteness approaches on which comment was sought, described above, because they may potentially result in incorrect conclusions regarding violations or the lack thereof. Because the number of valid daily concentration values remaining after even only a few missed days of monitoring would be quite small, a missing sample on a high-concentration day might make a confidence interval derived from the available data appear smaller than the actual variability of the daily concentrations, leading to an incorrect conclusion about the probability of a NAAQS violation. EPA may continue to study these or similar approaches for application in future NAAQS reviews. Another possible application of these approaches could be to inform the Administrator's case-by-case decisions on whether to use data that are incomplete for comparison to the NAAQS, as was proposed and as the final rule allows the Administrator to do.[89]

D. Scaling Factors To Relate Pb-TSP and Pb-PM_{10}

1. Proposed Provisions

EPA proposed that Pb-PM_{10} monitoring could be conducted to meet Pb monitoring requirements at the option of the monitoring agency, but that site-specific scaling factors would have to be developed to adjust the Pb-PM_{10} concentrations to represent estimated Pb-TSP concentrations before comparison to the level of the Pb-TSP NAAQS. One year of side-by-side measurement with both types of samplers would be required to collect paired data for developing these scaling factors, and Pb-TSP monitoring could not be discontinued at a Pb-PM_{10} monitoring site until the factor for that site had been approved. The proposed Appendix R contained detailed requirements for the number of data pairs successfully collected during the year of testing, the degree of correlation required between the two types of measurements, and the stability of the ratio of concentration averages from month to month, and also provided the formula for calculating the scaling factor.

EPA also asked for comment on the possibility of adopting a default scaling factor, or a set of factors applicable in different situations, instead of requiring the development of site-specific factors. EPA noted in the proposal that paired Pb-TSP and Pb-PM_{10} data from three historical monitoring sites suggested that site-specific scaling factors for source-oriented monitoring sites may vary between 1.1 and 2.0, but that the range may also be greater. EPA asked for comment on possible default scaling factor values within a range of 1.1 to 2.0 for application to Pb-PM_{10} data collected at source-oriented monitoring sites. EPA also noted in the proposal that it appears that site-specific factors generally have ranged from 1.0 to 1.4 for non-source-oriented monitoring sites (with the factors for three sites ranging from 1.8 to 1.9), and that the ratios may be influenced by measurement variability in both samplers as well as by actual air concentrations. EPA asked for comment on possible default scaling factor values within a range of 1.0 to 1.9 for application to Pb-PM_{10} data collected at monitoring sites that are not source-oriented.

2. Comments on Scaling Factors

Many commenters addressed the scaling factor issues raised in the proposal, often as part of overarching comments on the interrelated issues of the choice of indicator[90], whether and for what locations the final rule should allow Pb-PM_{10} monitoring instead of TSP-Pb monitoring, and whether and how Pb-PM_{10} data, if collected, should be considered in determining compliance with or violation of the Pb-TSP NAAQS. Comments on the specific subject of scaling factors to relate Pb-PM_{10} measurements to Pb-TSP concentrations are addressed here. Other comments related to the Pb-PM_{10} versus TSP-Pb monitoring and data use aspects of the proposal are addressed in section IV.E.

Comment on scaling factors were overwhelmingly negative towards EPA's proposal to allow Pb-PM_{10} monitoring in place of Pb-TSP monitoring at any site on the condition that the monitoring agency first develop a site-specific scaling factor. Most commenters also did not support the alternative of establishing default scaling factors. Some commenters proposed that instead of allowing Pb-PM_{10} monitoring in place of Pb-TSP monitoring and then applying site-specific or default scaling factors to Pb-PM_{10} concentrations before comparison to the NAAQS, Pb-PM_{10} monitoring only be allowed at certain types of sites.

Some commenters said that it would be burdensome on state monitoring agencies to have to develop site-specific scaling factors because two kinds of monitoring equipment would have to be deployed at each site, one set of which would become superfluous whether or not a scaling factor was successfully developed. Concerns were also expressed that the actual ratio of the two parameters could vary over time, and therefore that EPA's proposal that a scaling factor could be used indefinitely once developed on the basis of one year of paired measurements would not be protective of public health. No comments were received on the specifics of the proposal regarding the amount and type of data that would be required to be collected or the specific correlation criteria and formula for developing a site-specific scaling factor.

The final rule does not contain any provisions for the development of site-specific scaling factors, for two reasons. The proposed requirement for a year of paired measurements would require considerable initial investment of equipment, labor time, and laboratory costs by a monitoring agency for paired measurement of both Pb-PM_{10} and Pb-TSP in hopes of obtaining the option of indefinitely monitoring only for Pb-PM_{10} thereafter. The lack of any interest in this approach on the part of monitoring agencies is one of the reasons it is not included in the final rule. Second, given the considerations leading to retaining Pb-TSP as the indicator for the NAAQS, considerable caution should be applied on any scaling factor approach because of the uncertainty associated with the development and use of scaling factors.

Since issuing the proposal, EPA has engaged a statistical consultant to review whether the proposed criteria regarding the amount and type of data that would be required to be collected and the specific correlation criteria and formula for developing a site-specific scaling factor were practical and scientifically sound. This assessment examined both the proposed criteria which were structured around the proposed monthly averaging time and a modified approach structured around a 3-month averaging time. The consultant's report has been submitted to the public docket.[91] This assessment was able to ''test drive'' the proposed criteria and formula only on a relatively small number of data sets containing a sufficient number of Pb-TSP and *high-volume* Pb-PM_{10} data pairs, and as such could not be completely definitive regarding the merits of the criteria and formula when applied to *low volume*

[89] No public comment was received on this provision.

[90] Comments regarding whether Pb-TSP or Pb-PM_{10} should be the indicator for the NAAQS and EPA's response to them are discussed in section II.C.1.

[91] Scaling Factor: PM_{10} versus TSP, Neptune and Company, Inc., Final Report, September 30, 2008.

Pb-PM_{10} data. Also, EPA does not necessarily endorse every aspect of the assessment or its conclusions even apart from this data type disparity. However, EPA believes based on our review of the consultant's work that there are significant unresolved issues with the proposed criteria and formula with respect to their scientific adequacy and appropriateness for the intended purpose, and that these issues could result in not providing the protection intended by the Pb NAAQS.[92] This is another reason why the site-specific scaling factor approach is not included in the final rule. One finding in the consultant's report is that among the 21 sites where sufficient paired exist to meet the proposed data requirements for development of site-specific scaling factors, the proposed criteria for month-to-month consistency of the ratios of the two types of measurement and for overall correlation between the two measurements across the year were met at only four sites, three of which appear to be non-source-oriented.[93] For the non-source-oriented sites and years of data for which all the proposed criteria were met, the scaling factors fell in the range of 1.2 to 1.4. This indicates that while the observation at proposal was true that there are three non-source-oriented sites with some paired data that result in ratios in the range of 1.8 to 1.9, the data from these sites would be inadequate for developing site-specific scaling factors under the criteria of the proposed rule.

The alternative approach of establishing default scaling factors was also opposed by virtually all commenters who addressed it, and no commenter supported any specific default factor or set of default factors. Many commenters asserted that no reliable default factor or factors could be developed and that all Pb measurements for comparison to the NAAQS should be Pb-TSP measurements because of the possible presence of ultra-coarse particles containing significant amounts of Pb. One commenter did not oppose the concept of default scaling factors but even that commenter said that EPA should conduct more testing before developing such factors. A number of commenters said that if scaling factors are used, they should be conservative, health protective factors to ensure that the use of Pb-PM_{10} monitors does not result in increased lead exposures; some of these commenters pointed to the case of a particular Pb monitoring site that was reported in the preamble to the proposed rule to have a scaling factor of 2.0. Other commenters argued that the data set from the site (in East Helena, MT) suggesting such a high ratio of Pb-TSP to Pb-PM_{10} was not representative of the current emissions profile of sources subject to emission standards adopted since that data set was collected, and that a scaling factor for future application should be lower than 2.0.

The final rule does not provide a default scaling factor or set of factors for relating the two types of Pb concentration measurements. Any default factor or factors would be subject to greater technical pitfalls than would site-specific scaling factors. EPA believes, considering the data presented at the time of the proposal, the comments, and the consultant's assessment described above, that the variability and thus the uncertainty in the relationship of the two types of Pb measurement is not conducive to developing a default scaling factor to address all situations in which it might be applied, unless it were set so large that it effectively discouraged Pb-PM_{10} monitoring (see below). Also, while in concept multiple default scaling factors applicable to different situations should be more successful in avoiding this problem, they could never be as good as site-specific factors about which EPA has the technical reservations described above, in addition to the practical reservations expressed by all monitoring agencies which commented on the subject. For these reasons, EPA is not adopting either site specific or default scaling factors for use as described in the proposal.

However, as discussed below, the final rule does permit the use of Pb-PM_{10} monitoring, and direct comparison of Pb-PM_{10} concentrations to the Pb-TSP NAAQS, in certain situations in which EPA can be confident that such monitoring and data comparisons will in fact be a protective approach, and where such monitoring may be attractive for other reasons that were described in the proposal and also noted by commenters. Several commenters supported allowing Pb-PM_{10} monitoring to meet Pb monitoring requirements in some situations and, in only those situations, comparing Pb-PM_{10} data directly without any scaling factor to the Pb-TSP indicator-based NAAQS. The thrust of these comments was that this approach to making use of Pb-PM_{10} monitors and their data would be an acceptably protective approach provided that Pb-PM_{10} monitoring and associated comparison to the NAAQS is limited to sites where there is good reason to expect that Pb-TSP concentrations are well below the level of the NAAQS and/or that based on the nature of the nearby sources the fraction of ultra-coarse Pb in Pb-TSP would be low. Some commenters recommended this approach to monitoring only if the NAAQS has been set at a particular level. Because an appropriate response to these comments involves many of the same facts and considerations that EPA has taken into account in addressing the comments explicitly about scaling factors, above, we address these comments here as part of the discussion of data interpretation, noting that section V of this preamble discusses in more detail the changes to 40 CFR 58 associated with our disposition of these comments.

EPA agrees that given the several attractions of low-volume Pb-PM_{10} monitoring as far as accuracy and representativeness over an area, it is appropriate to allow for the use of Pb-PM_{10} monitors instead of Pb-TSP monitors at locations where there is very little likelihood that Pb-TSP levels will exceed the NAAQS. We also believe that in general the non-source-oriented monitoring sites required in CBSAs with populations over 500,000 (see Section V) meet this condition. Our experience with paired data at apparently non-source-oriented sites, as detailed in the Staff Paper and the preamble to the proposal, augmented by the statistical consultant's report mentioned above, supports the conclusion that the ratio of Pb-TSP concentrations to Pb-PM_{10} concentrations at non-source-oriented sites is consistently within the range of 1.0 to 1.4.[94] The corresponding range of

[92] The issues include but are not limited to the following: The available paired data sets with enough pairs of data to apply the criteria are all from sites where Pb-TSP concentrations were well below the final level of the revised NAAQS so there is uncertainty about how well they represent sites for which the accuracy of the scaling factor is critical to compliance with or violation of the NAAQS; many of the available data sets were not able to meet the proposed criteria for the correlation between parameters and for consistency of the ratio between parameter averages from month to month, meaning that no valid scaling factors could be derived following the terms of the proposed Appendix R; the proposed methods are sensitive to how measurements below the method detection limit are reported and it is not clear how this reporting was done in the available sets of paired data, and EPA did not propose any particular reporting conventions for public comment; the site-specific scaling factors in some cases varied from year to year in those few cases where more than one year had enough pairs of data; and there are indications that a linear relationship between the two parameters with a non-zero intercept may be a better representation than a scaling factor which inherently presumes a zero intercept.

[93] The consultant's report does not characterize the orientation of the monitoring sites, but based on other information it appears that sites 060250005, 260770905, and 261390009 are non-source oriented.

[94] Of 20 sites with paired data which EPA believed at the time of the proposal to not be influenced by nearby industrial sources, only 3 had

ultra-coarse Pb fraction is zero to 0.3. Also, a new EPA staff analysis, completed since proposal, of recent Pb-TSP concentrations at existing monitoring sites that appear to be non-source-oriented (including all sites with complete data from at least one Pb-TSP monitor, not just sites with paired data) shows that nearly all of them have been well below the final level of the NAAQS; in fact, nearly all have had 3-month average Pb-TSP concentrations in 2005–2007 that do not exceed 50 percent of the NAAQS.[95] Therefore there is, in the Administrator's judgment, little risk to the protective effect of the NAAQS in allowing the use of Pb-PM_{10} monitors at such sites and in comparing the Pb-PM_{10} measurements directly to the Pb-TSP NAAQS. The final rule allows this, with two safeguards to further ensure the protection intended by the Pb-TSP NAAQS. The first protection is a pre-condition that the available Pb-TSP monitoring data at the site during the previous three years, if any are available, do not show any 3-month average concentrations equal to or greater than 0.10 μg/m^3, which is 67 percent of the final NAAQS level.[96] Thus unlike the proposed use of scaling factors, where an approved scaling factor could have been applied to any and all recorded measured levels of Pb-PM_{10}, increasing the concern over the protectiveness of this approach, here the use of Pb-PM_{10} data does not raise similar concerns. To guard against the possibility that any of these required sites may be different in a way that contradicts the previous experience at such sites and against the possibility that source conditions around one or more of these monitoring sites may change over time, the final rule also provides that if any 3-month average concentration of Pb-PM_{10} is ever observed to be equal to or greater than 0.10 μg/m^3, a Pb-TSP monitor must be installed.[97] This 33 percent margin against the level of the NAAQS is protective for the long run situation, given that the available data strongly suggest that scaling factors will rarely if ever be greater than 1.4 at non-source-oriented sites. If the 3-month average Pb-PM_{10} concentration at a site was below 0.10 μg/m^3 and the scaling factor at that site was 1.4, the 3-month Pb-TSP concentration would be below the level of the NAAQS. EPA notes that some commenters suggested that this flexibility be pre-conditioned on there being site-specific affirmative evidence that Pb-TSP concentrations are less than 50 percent of the NAAQS. However, for many of the required monitoring sites of this type there will be no pre-existing Pb monitoring data and in the absence of a dominant nearby industrial source attempts to estimate Pb concentrations using air quality modeling techniques would be very uncertain. EPA believes that the evidence from the many existing non-source-oriented sites is sufficient to support allowing this flexibility without a site-specific hurdle, other than the provision tied to existing monitoring data if there are any.

EPA has also considered whether any of the required source-oriented sites should be allowed to be monitored for Pb-PM_{10} rather than Pb-TSP, also with the Pb-PM_{10} concentrations compared directly to the Pb-TSP NAAQS. As explained in Section V, the final requirements for monitoring near sources of Pb are based on the quantity of Pb emitted being above an emissions threshold. We are extending the allowance for the use of Pb-PM_{10} monitors to allow Pb-PM_{10} monitors without the use of scaling factors for source-oriented monitors where Pb concentrations are expected to be less than 0.10 μg/m^3 (based on modeling or historic data) and where the ultra-course Pb fraction is expected to be low. We are also requiring, as for non-source-oriented sites, that a Pb-TSP monitor be required at a source-oriented site if at some point in the future the Pb-PM_{10} monitor shows that Pb-PM_{10} concentrations are equal to or greater than 0.10 μg/m^3.[98] A state may also operate non-required Pb monitors at any other locations of its choosing, and these may be of any type.

3. Conclusions on Scaling Factors

The final version of Appendix R eliminates all reference to scaling factors. As explained in detail in section V, the final rule allows Pb-PM_{10} monitoring as a surrogate for Pb-TSP monitoring under certain specified conditions, with continuation of such monitoring being contingent on measured 3-month average Pb-PM_{10} concentrations remaining without application of any scaling factor staying less than 0.10 μg/m^3. Section IV.E discusses how Pb-PM_{10} monitoring data will be used as a surrogate for Pb-TSP in comparisons to the Pb-TSP NAAQS to determine compliance with or violation of the NAAQS.

E. Use of Pb-TSP and Pb-PM_{10} Data

1. Proposed Provisions

The proposed text of Appendix R provided that complete Pb-TSP data would be given precedence over both incomplete and complete (scaled) Pb-PM_{10} data, when both were collected in the same month at the same site, and prohibited the mixing of the two types of data in calculating the average Pb concentration for a single month. Pb-TSP data would be used in preference to Pb-PM_{10} data to form a monthly average Pb concentration whenever the Pb-TSP data meets the test for completeness and valid monthly average, i.e., whenever 75 percent of scheduled samples have valid data or one or the other of the two diagnostic tests in the case of less than 75 percent completeness results in a valid monthly average. If the Pb-TSP data were not complete enough to allow development of a monthly average, the available scaled Pb-PM_{10} data from the site for that month would be used provided they were complete enough. Scaled Pb-PM_{10} data could be used to show both compliance and violation of the NAAQS.

2. Comments on Use of Pb-TSP and Pb-PM_{10} Data

No comments were received specifically on the proposed provisions of Appendix R addressing the precedence between Pb-TSP and Pb-PM_{10} data. However, the elimination of scaling factors from the final rule and the inclusion of flexibility for Pb-PM_{10} monitoring only in limited situations, done by EPA in the final rule in response to comments summarized above, have required EPA to reconsider the proposed provisions on the use of

ratios of average concentrations of Pb-TSP to Pb-PM_{10} greater than 1.4. One of these sites had only 13 data pairs. The other two sites had very low concentrations of both parameters, such that the ratio may reflect the influence of data rounding/truncation or censoring of data below the method detection limit more than actual atmospheric concentration ratios. Also, these paired data were from 2001 or earlier. (Development of Pb-PM_{10} to Pb-TSP Scaling Factors, Mark Schmidt, 4/22/08.) Also, as noted above, the data from these sites are not adequate for the development of site-specific scaling factors if the proposed criteria for such data are applied to them.

[95] M. Schmidt and P. Lorang (October 15, 2008). Memo to Lead NAAQS Docket, Analysis of Expected Range of Pb-TSP Concentrations at Non-Source Oriented Monitoring Sites in CBSAs with Population Over 500,000.

[96] Based on the analysis described in the memo referenced in the previous footnote, EPA estimates that this provision might have the effect of prohibiting the use of Pb-PM_{10} monitoring for at most only a few existing Pb monitoring sites which otherwise might be eligible for Pb-PM_{10} monitoring instead of Pb-TSP monitoring.

[97] When the Pb-TSP monitor is installed, the monitoring agency would have the option of discontinuing the Pb-PM_{10} monitor, and we expect that most agencies would do so for cost reasons.

[98] If three years of Pb-TSP monitoring results in no 3-month average Pb concentration equal to or greater than 0.10 μg/m^3, as might occur after the source improves its control of Pb emissions, the site would again be eligible for Pb-PM_{10} monitoring.

Pb-PM_{10} data and to make changes in the final version of Appendix R.

First, EPA has considered whether a comparison of Pb-PM_{10} monitoring data to the NAAQS should be able to result in a conclusion that the NAAQS has been violated if the comparison shows that a 3-month average Pb-PM_{10} concentration is above the level of the Pb-TSP NAAQS. This situation could occur at a site that is required by the final rule's Pb monitoring requirement which is allowed to use Pb-PM_{10} monitoring in place of Pb-TSP monitoring, although EPA believes it is unlikely given the preconditions in the final rule regarding which required sites may use Pb-PM_{10} monitoring. It might also occur at a non-required site, where the rule does not attempt to restrict the monitoring agency's flexibility to use Pb-PM_{10} monitoring and thus a monitoring agency might choose not to adhere to the same preconditions. Given that a Pb-PM_{10} monitor will generally capture somewhat less or at most the same quantity of Pb as would a Pb-TSP monitor on a given day, EPA believes that if a 3-month average of Pb-PM_{10} concentrations is based on data that meets the 75 percent completeness test, including the associated diagnostic data substitution tests described in IV.B, and is above the level of the NAAQS, that situation should be considered to be a NAAQS violation.

This should be the case even if a Pb-TSP monitor at the same site has recorded a complete, valid 3-month average Pb-TSP concentration below the NAAQS for the same 3-month period. As just stated, a Pb-PM_{10} monitor will generally capture somewhat less or at most the same quantity of Pb as would a Pb-TSP monitor on a given day. While it is conceivable that a malfunction of a Pb-PM_{10} monitor, an operator error, or simple variability could cause a single measured Pb-PM_{10} concentration to be higher than a valid same-day collocated Pb-TSP concentration measurement, EPA expects based on experience that this will be rare, particularly because 40 CFR part 58 appendix A and EPA quality assurance guidance contain required and recommended procedures to avoid equipment malfunctions and operator errors and to invalidate any data affected by them before submission to EPA's air quality data base. Also, since 3-month averages will be based on multiple measurements, a significant effect on 3-month average concentrations from such factors is an even more remote possibility. EPA believes that the only situation at all likely to arise in which a complete 3-month average of Pb-PM_{10} indicates a NAAQS violation while a complete 3-month average of Pb-TSP for the same period does not would be when the Pb-PM_{10} average includes more days of monitoring than the Pb-TSP average, and those additional days tend towards high concentrations. This can occur if the Pb-PM_{10} measurements are being taken on a more frequent schedule, if they are missing fewer days of scheduled data than for the Pb-TSP measurements (counting make-up samples), or if more extra samples are taken for Pb-PM_{10} than for Pb-TSP. Regardless of which cause or causes are responsible, EPA believes that the Pb-PM_{10} average based on more days of sampling would generally be the more robust indication of ambient concentrations, and the site should be considered to have violated the NAAQS.

Next, EPA has considered whether a comparison of Pb-PM_{10} monitoring data to the NAAQS should be able to result in a conclusion that the NAAQS has been met if the comparison shows that all the 3-month average Pb-PM_{10} concentrations over a 3-year period are below the level of the Pb-TSP NAAQS and there is no Pb-TSP data showing a violation, or should such a comparison only lead to the more limited conclusion that there has not been a demonstrated NAAQS violation.[99] In considering this issue, EPA notes that while the final rule allows the use of Pb-PM_{10} monitoring in place of Pb-TSP monitoring only at required non-source-oriented monitoring sites that by their nature are expected to have a low fraction of ultra-coarse Pb, even a low fraction is not a zero fraction. Also, the expectation of a low ultra-coarse fraction may turn out to be incorrect due to unexpected causes. Also, monitoring agencies may also deploy Pb-PM_{10} monitors at non-required sites which may have higher or unknown fractions of ultra-coarse Pb. Appendix R must anticipate the availability of data from such sites, as EPA believes that such data should not be ignored and that states should know in advance how it will be used if collected. Because Pb-PM_{10} data may include data from sites with non-zero ultra-coarse fractions and may include data from sites with high or unknown ultra-coarse factions, EPA believes it would undermine the protectiveness of the NAAQS to always allow any Pb-PM_{10} data from any monitoring site to demonstrate compliance with the NAAQS. Some site applicability restriction and/or compliance margin when using Pb-PM_{10} data to show compliance would be needed to avoid undermining the protectiveness of the NAAQS. The technical issues to be overcome in designing site applicability restrictions and/or compliance margins would be the same as the issues that arise when considering default scaling factors, described above.

EPA is also mindful that the distinction between a finding of compliance with the NAAQS and not making a finding of violation is much more theoretical than practical. The distinction is not important to the initial stages of the implementation process for a revised NAAQS, because (1) by the time of the initial designations very few Pb-PM_{10} monitoring sites will have three years of data so a finding of compliance would not be possible anyway [100], and (2) there is no practical difference in planning or implementation requirements between areas that have been found to be in compliance with the NAAQS and areas for which it can only be said that they have not been found to be in violation of the NAAQS. However, later, for an area initially designated nonattainment, an affirmative finding that the area is complying with the NAAQS is required in order for the area to be redesignated attainment (also referred to as maintenance) after emission controls are implemented. In the latter situation, however, a Pb-TSP monitor should be operating at any site that has initially shown a violation based on either Pb-TSP or Pb-PM_{10}, since Pb-TSP monitoring must begin at any site where Pb-PM_{10} concentrations have exceeded even 50 percent of the NAAQS. This makes it moot whether Pb-PM_{10} data alone can be used to redesignate a nonattainment area to attainment after emission controls are implemented. In light of the technical issues and the lack of any substantive consequences, the final version of Appendix R does not allow Pb-PM_{10} data to be used to show affirmative compliance with the NAAQS.

The above discussion addresses the compliance versus violation consequences of comparing Pb-PM_{10} and Pb-TSP data to the Pb-TSP NAAQS. EPA has also considered the issue of how design values should be determined when there is only Pb-PM_{10} data or there is a mixture of Pb-PM_{10} data and Pb-TSP data for a single monitoring site over a given period. In

[99] Such a comparison based on actual Pb-TSP data would of course be able to support a compliance conclusion, because Pb-TSP is the actual indicator for the NAAQS.

[100] Only a handful of low-volume Pb-PM_{10} monitoring sites are now operational none of which indicate NAAQS violations. In addition, any sites which begin operation in response to the final monitoring requirements cannot collect three years of data by the time designations must be completed.

addition to conveying the compliance or noncompliance status of a monitoring site, design values are also used as an informative indicator of pollutant levels more generally. For the revised Pb NAAQS, the design value in simple terms is the highest valid 3-month average concentration at a monitoring site over whatever period of three years is being reported.[101] It is necessary to be specific in Appendix R about whether and when Pb-PM_{10} data can be used in the calculation of the design value. In the proposal, the simple principle applied was that complete Pb-TSP data for a month or quarter always would have precedence over scaled Pb-PM_{10} data, but that in the absence of complete Pb-TSP data, scaled Pb-PM_{10} data would be used regardless of the resulting value of the design value. For the same reason described above that Pb-PM_{10} data will not be allowed to support a finding of compliance with the NAAQS, it would be inappropriate to use such data to develop a design value whose value is below the level of the NAAQS. Therefore, the final version of Appendix R provides that the only situation in which Pb-PM_{10} data will be used to calculate the design value is when doing so results in a higher design value than using only Pb-TSP data and that design value is above the level of the NAAQS.

3. Conclusions on Use of Pb-TSP and Pb-PM_{10} Data

The final version of Appendix R specifies that the NAAQS is violated whenever Pb-PM_{10} data or Pb-TSP data result in a 3-month average concentration above the NAAQS level, but that compliance with the NAAQS can only be demonstrated using Pb-TSP data. Pb-PM_{10} data will be used in the calculation of a design value only when doing so results in a higher design value than using only Pb-TSP data and that design value is above the level of the NAAQS.

F. Data Reporting and Rounding

1. Proposed Provisions

EPA proposed that individual daily concentrations of Pb be reported to the nearest thousandth μg/m³ (0.xxx) with additional digits truncated, and that monthly averages calculated from the daily averages would be rounded to the nearest hundredth μg/m³ (0.xx). Decimals 0.xx5 and greater would be rounded up, and any decimal lower than 0.xx5 would be rounded down. E.g., a monthly average of 0.104925 would round to 0.10 and a monthly average of 0.10500 would round to 0.11. Because the proposed NAAQS level would be stated to two decimal places, no additional rounding beyond what is specified for monthly averages would be required before a design value selected from among rounded monthly averages would be compared to the level of the NAAQS.

2. Comments on Data Reporting and Rounding

No comments were received on this aspect of the proposal.

3. Conclusions on Data Reporting and Rounding

The final version of Appendix R differs from that proposed because the proposed version addressed a single month as the averaging time for the NAAQS and the final NAAQS is based on a 3-month average concentration. In the preamble to the proposal, EPA did not specifically address whether and how, in the case of the NAAQS being based on a 3-month averaging time, calculated monthly averages would be rounded before being used to calculate the 3-month average. The final version of Appendix R specifies that all digits of the monthly average shall be retained for the purpose of calculating the 3-month average, with the 3-month average then rounded to the nearest hundredth μg/m³, i.e., 3-month average decimals 0.xx5 and greater would be rounded up and any decimal lower than 0.xx5 would be rounded down. Because individual monthly averages are never compared to the level of the NAAQS there is no need to specify a rounding convention for them, and retaining all digits until the final comparison of the 3-month average to the NAAQS allows a more precise determination of compliance compared to rounding at both the monthly and 3-month levels.

G. Other Aspects of Data Interpretation

One implication of the selection of a rolling 3-month period as the averaging time of the NAAQS is that there will be two 3-month periods that span each pair of adjacent calendar years: November-January and December-February. EPA has considered whether, for any three-calendar-year period, the 3-month averaging periods including one or both of the two months of the year prior to those three years and/or the averaging periods including one or both of the two months following those three years will be included in determining whether a monitoring site has met or violated the NAAQS. This issue was not discussed in the proposal, because the monthly average and calendar quarterly average options discussed in the proposal do not raise this issue. The final version of Appendix R provides that the 3-month averages which include either of the two months prior to a three-calendar-year period will be associated with that 3-year period, and that the 3-month averages which include either of the two months after the three-calendar-year period will not be associated with it. The latter two months would be within the next 3-year period and their data would affect compliance during that next 3-year period. Thus, for example, the thirty-six 3-month averages that will be considered in determining compliance with the NAAQS for the 3-year ''2010–2012'' evaluation period will be based on data from November and December of 2009, and all of 2010, 2011, and 2012. Data from November 2009 will be used as part of the calculation of one 3-month average, and data from December 2009 will be used as part of the calculation of two 3-month averages. Data from November and December of 2012 will be used but only for 3-month averages which are made up solely of months in 2012. Thus, for the 2010–2012 period, November 2009 through January 2010 is the first 3-month period and October through December 2012 is the last 3-month period.

This approach has been selected for practical reasons, because the once-per-year deadline for certifying data submitted to AQS means that data from January and February of the year after a three-calendar-year period will most often still be preliminary and uncertified as to completeness and accuracy for 12 months beyond when data from the three-calendar-year period itself (and the two previous months) are final and ready to be used for compliance determinations.

Generally, a violation will have occurred if any of the 36 three-month average concentrations of either Pb-TSP or Pb-PM_{10} exceeds the level of the NAAQS,[102] and a finding of compliance will require that all 36 3-month averages of Pb-TSP be at or below the level of the NAAQS. The final Appendix R addresses the special situation of a new monitoring site which has started sampling by January 15 of a certain year. After the first three years of data collection, only 34 3-month average concentrations will be available. In this

[101] It is also possible for a period of less than three years to have a valid design value, but only if the procedures in Appendix R when applied to that shorter period result in a design value greater than the level of the NAAQS. It is possible to establish a violation of the NAAQS on a monitoring period as short as three months but three years are needed to establish compliance with the NAAQS.

[102] A violation will exist as soon as any 3-month average exceeds the level of the NAAQS. It is not required that three years of data collection be completed before a site can be found in violation. This is consistent with the proposal.

situation, Appendix R provides that a finding of compliance will be made if all 34 available 3-month average concentrations of Pb-TSP are at or below the level of the NAAQS.

As discussed in Section V on monitoring requirements, EPA proposed and is finalizing a change to the Pb monitoring requirements to no longer allow monitoring agencies to combine several daily Pb-TSP filters for chemical analysis, at required Pb monitoring sites.[103] The proposed Appendix R presumed this change and did not address how data from such ''composite'' samples would be used in comparisons to the NAAQS. However, on further reflection EPA believes that whatever composite sample data have been collected and submitted to AQS before the prohibition on using the composite sample approach takes effect should be considered for purposes of initial designations under the revised NAAQS, if those data fall within the period on which designations will be based. The final version of Appendix R therefore includes specific provisions addressing how to account for composite sample data in determining data completeness and in calculating a monthly and 3-month average concentration value. These provisions will also govern the use of any composite sample data that are collected at non-required monitoring sites, indefinitely. The only noteworthy issue EPA had to consider in developing these provisions was what to do when the submitted data for a monitoring site includes both a composite sample Pb value and one or more individual daily sample Pb values. Because it is impossible to tell the exact days represented by a composite sample, Appendix R specifies that either the composite sample or the available daily data (if complete daily data were collected) will be used depending on which has the lower pollutant occurrence code,[104] but they will not be combined because that might give double weight to some days.

V. Ambient Monitoring Related to Revised Lead Standards

We are finalizing several changes to the ambient air monitoring and reporting requirements for Pb to account for the revised NAAQS and to update the Pb monitoring network. Ambient Pb monitoring data are used for comparison to the Pb NAAQS, for analysis of trends and accountability in areas with sources that have implemented controls, in the assessment of control strategies, for evaluating spatial variation of Pb concentrations across an area, and as an input to health studies used to inform reviews of the NAAQS. Ambient data are collected and reported by state, local, and tribal monitoring agencies (''monitoring agencies'') according to the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section summarizes the proposed changes to the monitoring requirements in the May 20, 2008 notice of proposed rulemaking, the major comments received on the proposed changes, and the final changes to the Pb monitoring regulations being promulgated with this action. This section is divided into discussions of the monitoring requirements for the sampling and analysis methods (including quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

A. Sampling and Analysis Methods

We are finalizing changes to the sampling and analysis methods for the Pb monitoring network. Specifically, we are continuing to use the current Pb-TSP Federal Reference Method (FRM, 40 CFR part 50 Appendix G), but are finalizing a new Federal Reference Method (FRM) for monitoring Pb in PM_{10} (Pb-PM_{10}) for the limited situations where it will be permitted, lowering the Pb concentration range required during Pb-TSP and Pb-PM_{10} candidate Federal Equivalent Method (FEM) comparability testing, and finalizing changes to the quality assurance requirements for Pb monitoring. The following paragraphs provide background, rationale, and details for the final changes to the sampling and analysis methods.

1. Pb-TSP Method

No substantive changes are being made to the Pb-TSP method. The current FRM for Pb sampling and analysis is based on the use of a high-volume TSP FRM sampler to collect the particulate matter sample and the use of atomic absorption (AA) spectrometry for the analysis of Pb in a nitric acid extract of the filter sample (40 CFR 50 Appendix G). There are 21 FEMs currently approved for Pb-TSP.[105] All 21 FEMs are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.[106]

a. Proposed Changes

We stated in the NPR that if the final standard is based on Pb-TSP, we believed it would be appropriate to continue use of the current high-volume FRM for measuring Pb-TSP. We proposed to make several minor changes in 40 CFR 50 Appendix G to correct reference citations. However, we did not propose any substantive changes to Appendix G.

In addition, we stated in the NPR that we believe that low-volume Pb-TSP samplers might be superior to high-volume TSP samplers. We pointed out that presently, a low-volume TSP sampler cannot obtain FRM status, because the FRM is specified in design terms that preclude designation of a low-volume sampler as a FRM. We also suggested that a low-volume Pb-TSP monitoring system (including an analytical method for Pb) could be designated as a FEM Pb-TSP monitor, if side-by-side testing were performed as prescribed by 40 CFR 53.33. We proposed amendments to 40 CFR 53.33 (described below in section V.A.3) to make such testing more practical and to clarify that both high-volume and low-volume TSP methods could use this route to FEM status. We also held a consultation with the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee on approaches for the development of a low-volume TSP sampler FRM or FEM.

b. Comments on Pb-TSP Method

This section addresses comments we received on our proposal to continue the use of the Pb-TSP FRM as the monitoring method for the Pb NAAQS, and comments on the use of low-volume TSP samplers as either a FEM or FRM for Pb-TSP. We also received comments on a number of related topics that are not discussed in this section. We received comments on the use of Pb-PM_{10} as the Pb indicator, and those comments are addressed in Section II.C.1 of this preamble. We received comments on the use of scaled Pb-PM_{10},

[103] The FRM specification in the new Appendix Q for Pb-PM_{10} monitoring excludes the possibility of composite sampling for Pb-PM_{10}, so this in an issue that applies only to Pb-TSP.

[104] The pollutant occurrence code is a numerical code (1, 2, 3, etc.) used to distinguish the data from two or more monitors for the same parameter at a single monitoring site. For example, if a monitoring agency has been using both composite analysis for filters from one sampler and individual sample analysis for filters from a collocated sampler, data from these would be distinguished using this code. Choosing which set of data to use based on which has the lower code value is an approach chosen for its simplicity, to avoid specifying what would have to be a complicated set of procedures to determine which set of data or combination of the two sets actually is the more robust for determining whether the NAAQS is met.

[105] For a list of currently approved FRM/FEMs for Pb-TSP refer to: *http://www.epa.gov/ttn/amtic/criteria.html.*

[106] The 21 distinct approved FEMs represent less than 21 fundamentally different analysis methods, as some differ only in minor aspects.

or other ways to supplement Pb-TSP monitoring data with Pb-PM_{10} data, and those comments are addressed in Section IV.D, and in Section V.B of this preamble.

We received a number of comments on our proposal to continue the use of high-volume TSP samplers as the sampling method for Pb. In their comments on the proposed rule, CASAC reiterated their concerns over the measurement uncertainty due to effects of wind speed and wind direction on sampling efficiency.[107] These concerns were discussed in detail in our proposed rule, and as such are not reiterated here. However, CASAC stated that if the final level of the NAAQS were to be set at 0.10 μg/m³ or above, then the high-volume Pb-TSP sampler should be used. Some public commenters also stated similar concerns with the performance of the Pb-TSP sampler.

A large number of other commenters stated that the high-volume TSP sampler should continue to be the sampler for determining compliance with the Pb NAAQS. They expressed concerns that PM_{10} samplers would not capture ultra-coarse particles (i.e., particulate matter with an aerodynamic diameter greater than 10 μm), and could greatly underestimate Pb concentrations in the ambient air, especially near Pb sources.

Despite some limitations with sampler performance and consistent with CASAC advice for methods at the level of the NAAQS we have chosen, we believe the high-volume sampler is the most appropriate currently available sampler for the measurement of Pb-TSP in ambient air. Ultra-coarse particulate matter (larger than PM_{10}) can contribute to a significant portion of the total Pb concentration in ambient air, especially near Pb sources (Schmidt, 2008) where Pb-TSP concentrations may be as much as twice as high as Pb-PM_{10}. Furthermore, we believe the precision and bias of the high-volume TSP sampler are acceptable and similar to those for other PM samplers (Camalier and Rice, 2007).

We received several comments supporting the need for the development of a low-volume Pb-TSP sampler. However, in our consultation with CASAC's AAMM Subcommittee, we were cautioned against finalizing a new low-volume Pb-TSP FRM without an adequate characterization of the sampler's performance over a wide range of particle sizes.[108] We agree with the interest for a low-volume Pb-TSP sampler and the desire for such a sampler to be adequately characterized prior to being promulgated as a new FRM. Accordingly, we plan to further investigate the possibility of developing a low-volume FRM in the future.

c. Decisions on Pb-TSP Method

We are maintaining the current FRM and FEMs for Pb-TSP as the sampling and analysis methods for monitoring for the Pb NAAQS. As proposed, we are making minor editorial changes to 40 CFR 50 Appendix G (the FRM for Pb-TSP) to correct some reference citations. We are not making any other substantive changes to Appendix G.

2. Pb-PM_{10} Method

We are finalizing a new FRM for Pb-PM_{10} monitoring based on the use of the low-volume PM_{10C} FRM (40 CFR part 50, Appendix O) sampler coupled with energy dispersive x-ray fluorescence (XRF) as the analysis method. This section describes the proposed Pb-PM_{10} FRM, the comments we received, and the final Pb-PM_{10} FRM requirements being promulgated with this action.

a. Proposed FRM for Pb-PM_{10} Monitoring

We proposed a new Pb-PM_{10} FRM based on the use of the already promulgated PM_{10C} FRM coupled with XRF as the analysis method. We proposed to use the low-volume PM_{10C} sampler for the FRM for Pb-PM_{10} rather than the existing PM_{10} FRM specified by Appendix J, for several reasons. The low-volume PM_{10C} FRM sampler meets more demanding performance criteria (Appendix L) than are required for the PM_{10} samplers described in Appendix J. PM_{10C} samplers can be equipped with sequential sampling capabilities (i.e, the ability to collect more than one sample between operator visits). The low-volume PM_{10C} sampler can also precisely maintain a constant sample flow rate corrected to actual conditions by actively sensing changes in temperature and pressure and regulating sampling flow rate. Use of a low-volume sampler for the Pb-PM_{10} FRM would also provide network efficiencies and operational consistencies with the samplers that are in widespread use for the $PM_{2.5}$ FRM network, and that are seeing growing use in the PM_{10} and $PM_{10-2.5}$ networks. Finally, the use of a low-volume sampler is consistent with the comments and recommendations from CASAC and members of CASAC's AAMM Subcommittee (Henderson 2007a, Henderson 2008a, Russell 2008b).

We proposed XRF as the FRM analysis method because we believe that it has several advantages which make it a desirable analysis method. XRF does not require sample preparation or extraction with acids prior to analysis. It is a non-destructive method; therefore, the sample is not destroyed during analysis and can be archived for future re-analysis if needed. XRF analysis is a cost-effective approach that could be used to simultaneously analyze for many additional metals (e.g., arsenic, antimony, and iron) which may be useful in source apportionment. XRF is also the method used for the urban $PM_{2.5}$ Chemical Speciation Network (required under Appendix D to 40 CFR part 58) and for the Interagency Monitoring of Protected Visual Environments (IMPROVE) rural visibility monitoring program in Class I visibility areas, and is being considered by EPA for a role in $PM_{10-2.5}$ coarse speciation monitoring. Based on data from the $PM_{2.5}$ speciation monitoring program, the XRF analysis method when coupled with the low-volume PM_{10C} sampler, is expected to have an adequate method detection limit (MDL, the lowest quantity of a substance that can be distinguished from the absence of that substance) and meet the measurement uncertainty goals for precision and bias as determined through the data quality objective (DQO) analysis (Papp, 2008), as explained later in this preamble.

b. Comments on the proposed Pb-PM_{10} FRM

We received a number of comments on the proposed FRM for Pb-PM_{10}. In addition, the CASAC AAMM Subcommittee provided a peer review of the proposed Pb-PM_{10} FRM. The following paragraphs describe the comments received and our responses.

The CASAC AAMM Subcommittee agreed with our proposed use of the PM_{10C} sampler. Other comments on our proposed use of the low-volume PM_{10C} sampler for the Pb-PM_{10} FRM were in support of the PM_{10C} as an appropriate sampler for the FRM. We are promulgating the Pb-PM_{10} FRM based on the use of the low-volume PM_{10C} sampler.

We also received comments on our proposed use of XRF as the analysis method for the Pb-PM_{10} FRM, including comments from CASAC's AAMM

[107] Sampling efficiency refers to the percentage of total Pb (or PM) that is collected by the sampler. For the TSP sampler, research shows that the sampling efficiency varies for particulates greater than PM_{10} as a function of wind speed and wind direction.

[108] Proper characterization of a new Pb-TSP FRM sampler would require extensive wind-tunnel testing and field testing. Wind tunnel testing would be complicated by the difficulty in quantifiably generating and delivering precise amounts of ultra-coarse PM in a wind-tunnel setting.

Subcommittee during the peer review of the proposed FRM. Several commenters agreed with our proposed use of XRF as the analysis method, citing several of the advantages we identified in the preamble to the proposed rule. However, several other commenters suggested that Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) would be a more appropriate analysis method for the FRM.

The AAMM Subcommittee and other commenters raised concerns with the potential for measurement bias due to non-uniform filter loadings. They noted that the analysis beam of the XRF analyzer does not cover the entire filter collection area; therefore, it is possible for the measurement to be biased if the Pb particles deposit more (or less) on the edge of the filter as compared to the center of the filter. To address these concerns, EPA's Office of Research and Development (ORD) conducted qualitative and quantitative tests of filter deposits generated in the laboratory under controlled conditions. Although test results confirmed prior reports of formation of a deposition band at the circumference of the PM_{10C} filters, this band comprises only 5 percent of the filter's deposition area. Quantitative analysis of collected calibration aerosols in the 0.035 micrometer to 12.5 micrometer size range revealed that use of either a centrally located 10 mm or 20 mm spot size can accurately represent the filter's mean mass concentration within approximately 2 percent. Similar results were obtained using a $PM_{2.5}$ FRM sampler and a ''total particulate sampler'' (a $PM_{2.5}$ sampler with the internal separator removed). Based on these results, it can be concluded that any non-uniformity of particle deposition on PM_{10C} filters will represent a small fraction of the overall uncertainty in ambient Pb concentration measurement. As such, we believe the concerns associated with non-uniform filter loading are sufficiently addressed to allow XRF as an appropriate analysis method for the FRM.

The AAMM Subcommittee and other commenters suggested ICP-MS as an alternative to the XRF analysis method. Advantages identified with ICP-MS included the analysis of the entire filter deposit and a higher sensitivity (i.e., lower MDL.) We agree that the ICP-MS analysis method is also an appropriate method for the analysis of Pb. However, ICP-MS (and other analysis methods requiring the extraction of Pb prior to analysis) also has potential bias due to uncertainty in the percentage of total Pb that is extracted. While this bias can be minimized by use of very strong acids (i.e., hydrogen fluoride), many laboratories wish to avoid these strong acids due to the damage they can do to the analyzer and due to safety concerns. In addition, ICP-MS is a destructive method and samples cannot be saved for further analysis. We agree that the ICP-MS method is more sensitive than the XRF method. However, the XRF method detection limit provides sufficient sensitivity for use in determining compliance with the Pb NAAQS being promulgated today. As pointed out in our preamble to the proposed rule, we estimated the method detection limit for XRF and ICP-MS coupled with low-volume sampling to be 0.001 $\mu g/m^3$ and 0.00006 $\mu g/m^3$, respectively. No commenters disagreed with these estimates.

Several states requested approval for alternative analysis methods because their laboratories are already equipped to perform those analysis methods. Our decision to use XRF as the FRM analysis method does not prevent monitoring agencies from using alternative analysis methods. However, before these alternative analysis methods can be used they must be approved as FEMs for the measurement of Pb-PM_{10}. Monitoring agencies can seek FEM approval for alternative analysis methods by following the FEM requirements (40 CFR Part 53.33). In addition, we plan to approve (after conducting the necessary testing and developing the necessary applications ourselves) FEMs for ICP-MS and Graphite Furnace Atomic Absorption (GFAA) to support monitoring agencies that prefer to use these analysis methods.

We also received comments on the specific details of the proposed XRF analysis method. The AAMM Subcommittee and one other commenter raised concerns about the lack of a thin-film XRF National Institute of Standards and Technology (NIST)-traceable Pb standard. NIST currently offers Standard Reference Material (SRM) 2783, ''Air Particulate on Filter Media'', that is a polycarbonate filter that contains a certified concentration for Pb equivalent to 0.013 ± 0.002 $\mu g/m^3$. Calibration materials for XRF are not destroyed during analysis; therefore, the SRM should be stable over time and can be reused multiple times if properly handled and protected.

The AAMM Subcommittee raised concerns regarding lot-specific laboratory blanks, field blanks, and possible contamination of filters. The commenters suggested that the laboratory blanks (the results of Pb analysis of ''clean'' filters that have not been used in a sampler) that are used for XRF background measurement and correction be lot-specific. The addition of lot-specific laboratory blanks will help minimize contamination that may be due to new filter lots and the analytical system. A few commenters suggested the addition of field blanks in order to minimize the Pb contamination of filters in the field. Field blanks are filter blanks that are sent to the field and are placed into the sampler for the sampling duration without ambient air flow. We agree with the suggestions to make laboratory blanks lot-specific and to add the collection of field blanks. A comment to add annual MDL determinations and filter-lot specific MDL determinations was received. We agree that the addition of annual MDL estimates and lot-specific MDL determinations is an improvement to the proposed FRM text. In addition, several editorial comments were received that related to modifying existing statements to add clarity and help to ensure consistency across laboratories. We are making changes to the XRF analysis method to address these editorial comments.

We received one comment related to the need for data quality objectives (DQOs). We agree with the commenter on the need for DQOs for the Pb-PM_{10} FRM. Since the time of proposal, we have completed the DQO analysis to evaluate the acceptable measurement uncertainty for precision and bias. The DQO report is in the docket. As part of that process, the recommended goals for precision were defined as an upper 90 percent confidence limit for the coefficient of variation of 20 percent and the goals for bias were defined as an upper 95 percent confidence limit for the absolute bias of 15 percent. We have reflected this in our final regulation.

c. Decision on Pb-PM_{10} FRM

We are finalizing the FRM for Pb-PM_{10} as proposed with the exception of the following amendments and additions. Changes to the XRF analysis method are being made to address comments received during the public comment period and peer review of the proposed Pb-PM_{10} FRM. These changes include a revision to the Pb-PM_{10} FRM text to include reference to the SRM 2783 NIST-traceable calibration standard. The FRM text was modified to add a section that requires the collection of field blanks, and clarify that the laboratory blanks used for background measurement and correction shall be lot-specific. We added the requirements for annual MDL estimates and lot-specific MDL determinations. Several minor changes were made to address editorial comments received that related to modifying existing statements to add

clarity and help to ensure consistency across laboratories. Examples of these changes include the addition of other commercial XRF instrumentation vendors; clarification of the maximum filter loading for Pb analysis which is based on the maximum mass loading (200 μg/m^3) for a PM_{10C} sampler; inclusion of additional references for spectral processing methods; and clarification that the FRM applies specifically to Pb. A reference was included for additional guidance if multi-elemental analysis is performed. To ensure consistency in reporting uncertainties for Pb by XRF across laboratories, an equation to calculate uncertainties was added and follows the same procedure used for XRF in the $PM_{2.5}$ speciation program. Based on the DQO process, the FRM precision and bias requirements were modified to reflect the measurement uncertainty goals of 20 percent and 15 percent, respectively.

3. FEM Requirements

We are finalizing changes to the FEM requirements for Pb. These requirements will apply for both Pb-TSP and Pb-PM_{10} methods. This section discusses the proposed changes to the FEM requirements, comments received on the proposed changes, and the final FEM requirements being promulgated with this action.

a. Proposed FEM Requirements

The current FEM requirements state that the ambient Pb concentration range at which the FEM comparability testing must be conducted to be valid is 0.5 to 4.0 μg/m^3. Currently there are few locations in the United States where FEM testing can be conducted with assurance that the ambient concentrations during the time of the testing would exceed 0.5 μg/m^3. In addition, the Agency proposed to lower the Pb NAAQS level to between 0.10 and 0.30 μg/m^3. Consistent with this proposed revision, we also proposed to revise the Pb concentration requirements for candidate FEM testing to a range of 30 percent of the revised level to 250 percent of the revised level in μg/m^3. The requirements were changed from actual concentration values to percentages of the NAAQS level to allow the FEM requirements to remain appropriate if subsequent changes to NAAQS levels occur during future NAAQS reviews.

The current FEM does not have a requirement for a maximum MDL. In order to ensure that candidate analytical methods have adequate sensitivity or MDLs, we proposed adding a requirement for testing of a candidate FEM. The applicant must demonstrate that the MDL of the method is less than 1 percent of the level of Pb NAAQS.

We proposed to modify the FEM requirements for audit samples. Audit samples are the known concentration or reference samples provided by EPA and used to verify the accuracy with which a laboratory conducts the FRM analytical procedure before it may be compared to the candidate FEM. The current requirements are that audit samples be analyzed at levels that are equal to 100, 300, and 750 μg per spiked filter strip (equivalent to 0.5, 1.5, and 3.75 μg/m^3 of sampled air). We proposed to revise the levels of the audit concentrations to percentages (30 percent, 100 percent and 250 percent) of the level of the Pb NAAQS to provide for reduced audit concentrations that are more appropriate for a reduced level of the revised NAAQS.

The existing FEM requirements are based on the high-volume TSP sampler, and as such, refer to ¾-inch x 8-inch glass fiber strips. In order to also accommodate the use of low-volume sample filters, we proposed to add references to 46.2 mm filters where appropriate. For FEM candidates that differ only from the FRM with respect to the analysis method for Pb, pairs of these filters will be collected by a pair of FRM samplers.

b. Comments

We received few comments on the proposed amendments to the FEM requirements for Pb. One commenter suggested that the proposed MDL requirement, 1 percent of the NAAQS, was overly stringent, and that an MDL of 5 percent would be sufficient. Another commenter suggested that an MDL at 10 percent would be more achievable. After reviewing these comments, we have reconsidered the requirement for the MDL to be 1 percent of the NAAQS or less and now believe that the requirement may be unduly restrictive. The MDL represents an estimate of the lowest Pb concentration that can be reliably distinguished from a blank. The concept of the ''limit of quantitation'' (LOQ), the level at which we can reasonably tell the difference between two different values, is often used to determine the concentration at which we have confidence in the accuracy of the measurement. The LOQ is usually estimated at 5 to 10 times the MDL. At a MDL of 5 percent (i.e., 0.0075 μg/m^3), the maximum LOQ would still be less than one half of the NAAQS (i.e., 0.075 μg/m^3). We believe this is adequate for the purposes of determination of compliance with the NAAQS. The three most commonly used Pb-PM_{10} analysis methods (XRF, ICP-MS, and GFAA) all have estimated method detection limits below 5 percent of the revised Pb NAAQS. We note, however, that for areas where concentrations may frequently be well below the NAAQS such as at non-source-oriented sites it may be desirable to use a FEM with a more sensitive analysis method (such as ICP-MS) to assure fewer non-detect measurements and to provide better accuracy at concentrations well below the NAAQS.

We received two comments supporting the development and consideration of the use of continuous Pb monitors. We agree that the FEM testing requirements should include language regarding FEM testing and approval of continuous or semi-continuous monitors.

c. Decisions on FEM Requirements

We are finalizing the FEM requirements for Pb as proposed except for the addition of certain language including FEM testing and approval of continuous or semi-continuous monitors.

4. Quality Assurance Requirements

We are finalizing changes to the quality assurance (QA) requirements for Pb. These requirements will apply for both Pb-TSP and Pb-PM_{10} measurements. This section discusses the proposed changes to the QA requirements, comments received on the proposed changes, and the final QA requirements being promulgated with this action.

a. Proposed Changes

We proposed modifications to the quality assurance (QA) requirements for Pb in 40 CFR part 58 Appendix A paragraph 3.3.4 in order to accommodate Pb-PM_{10} monitoring. In addition, we proposed to consolidate several existing requirements for PM samplers (TSP and PM_{10} samplers) into paragraph 3.3.4 to clarify that these requirements also apply to Pb-TSP and Pb-PM_{10} samplers. The following paragraphs detail the QA requirements we proposed to amend.

The collocation requirement for all TSP samplers (15 percent of a primary quality assurance originations sites at a 1 in 12 day sampling frequency, paragraph 3.3.1) applies to TSP samplers used for Pb-TSP monitoring. These requirements are the same for PM_{10} (paragraph 3.3.1); thus, no changes are needed to accommodate low-volume Pb-PM_{10} samplers. However, to clarify that this requirement applies to Pb-PM_{10} monitoring, in addition to mass measurements for PM_{10}, we proposed to

add a reference to this requirement in paragraph 3.3.4. The current requirement for selecting the collocated site requires that the site be selected from the sites having annual mean concentrations among the highest 25 percent of the annual mean concentration for all sites in the network.

The sampler flow rate verifications requirement (paragraph 3.3.2) for low-volume PM_{10} and for TSP are at different intervals. To clarify that this requirement also applies to Pb monitoring (in addition to sample collection for TSP and PM_{10} mass measurements) we proposed to add a reference to this requirement in paragraph 3.3.4.

Paragraph 3.3.4.1 has an error in the text that suggests an annual flow rate audit for Pb, but then includes reference in the text to semi-annual audits. The correct flow rate audit frequency is semi-annual. We proposed to correct this error. We also proposed to change the references to the Pb FRM to include the proposed Pb-PM_{10} FRM.

Paragraph 3.3.4.2 discusses the audit procedures for the Pb analysis method. This section assumes the use of a high-volume TSP sampler, and we proposed edits to account for the proposed Pb-PM_{10} FRM.

We proposed to require one audit at one site within each primary quality assurance organization (PQAO) once per year. We also proposed that, for each quarter, one filter of a collocated sample filter pair from one site within each PQAO be sent to an independent laboratory for analysis, for a total of 5 audits per year. The independent measurement on one filter from each pair would be compared to the monitoring agency's routine laboratory's measurement on the other filter of the pair, to allow estimation of any bias in the routine laboratory's measurements.

b. Comments

We received one comment on the proposed QA requirements specifically addressing the overall sampling and analysis bias. The commenter was concerned that the proposal to implement one independent performance evaluation audit (similar to the $PM_{2.5}$ Performance Evaluation Program (PEP)) and then augment that sample with four samples from collocated precision site would be inadequate. The commenter suggested that in order for the audit program to be successful it would require the same independent laboratory be used by all monitoring agencies across the country.

We believe it is important to have a measurement of the bias of the overall method for Pb (including both sampling and analysis aspects). We proposed five audits per PQAO per year (one independent audit and four collocated samples all analyzed at an independent lab). This proposal was based on data evaluations of $PM_{2.5}$ bias information, and the assumption that no PQAO would have more than 5 Pb sites. However, we now recognize that some PQAO are likely to have more than 5 sites, and as part of our consideration of this comment, we are revising the audit requirements to require 1 additional audit per PQAO and an additional 2 collocated sample filters for PQAO's with more than 5 sites. This sampling frequency would parallel the $PM_{2.5}$ performance evaluation. Based on our review of $PM_{2.5}$ bias information, five audits per year for PQAOs with five or fewer monitoring sites provide an adequate assessment of bias over a 3-year period. We believe we can provide an adequate three-year estimate of bias with this approach since it will yield the same number of audit results as the $PM_{2.5}$ PEP program. In addition, the statistic used to assess bias for $PM_{10-2.5}$ and the gaseous pollutants (section 4.1.3) will be used for the Pb bias assessment and will be referenced in section 4.4.2. This will eliminate the need to assess bias by combining data from the flow rate audits and Pb audit strips as discussed in sections 4.4.2 through 4.4.5, so this assessment will be removed. The use of the flow rate audits and Pb audit strips will be able to be assessed separately using statistics already available in Appendix A. Sections 4.2.2 and 4.2.3 for flow rate information and section 4.1.3 will be used for the Pb strip assessment.

Like the $PM_{2.5}$ PEP program, we are planning to implement an audit program for monitoring agencies requesting federal implementation of the audits, but allow monitoring agencies to implement their own audit program. We plan to utilize one laboratory for the analysis of the Pb audit samples for those monitoring organization requesting federal implementation of these audits. However, we expect some states will elect to implement their own audits. Independent laboratory services will be offered to monitoring organizations that are self-implementing this performance evaluation program, however, they may use other independent labs. Based on the current $PM_{2.5}$ PEP program, we expect the majority of monitoring agencies will elect to make use of the federally implemented audit program.

We also received comments on our proposed precision and bias goals from individual members of the CASAC AAMM Subcommittee as part of the consultation on March 25, 2008. The AAMM Subcommittee members indicated that we should base the precision and bias goals on the findings of the ongoing DQO analysis identified in our proposal. We have completed the DQO analysis as described in the proposed rule, and a copy of the report is in the docket for this rule. Based on the findings from the DQO analysis, we are finalizing a goal for precision and bias of 20 percent and 15 percent, respectively. These values allow for slightly higher uncertainty than the proposed values and reflect the finding that the existing high-volume samplers may not routinely be capable of meeting the proposed precision and bias goals.

c. Decisions on Quality Assurance Requirements

We are finalizing amendments to the QA requirements for Pb measurements as proposed with the following differences. Based on the DQO analysis, the goal for acceptable measurement uncertainty will be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 20 percent and as an upper 95 percent confidence limit for the absolute bias of 15 percent. The evaluation of precision will also be limited to those data greater than or equal to 0.02 $\mu g/m^3$. These goals are included in section 2.3.1 of 40 CFR Part 58 Appendix A. We are requiring 1 PEP audit per year per PQAO with 5 or fewer sites, and 2 PEP audits per year per PQAO with more than 5 sites. Due to the addition of the Pb performance evaluation, a reference to the statistical assessment of bias used for $PM_{10-2.5}$ and the gaseous pollutants (section 4.1.3) has been included in section 4.4.2 and the requirement for the bias calculation using the Pb strips in combination with the flow rate audits, as discussed in sections 4.4.2 through 4.4.5, has been removed and sections 4.2.2 and 4.2.3 have been used to assess flow rate information and section 4.1.3 has been used for the Pb strip laboratory bias assessment.

B. Network Design

As a result of this Pb NAAQS review and the tightening of the standards, EPA recognizes that the current network design requirements are inadequate to assess compliance with the revised NAAQS. Accordingly, we are promulgating new network design requirements for the Pb NAAQS surveillance network. The following sections provide background, rationale, and details for the final changes to the Pb network design requirements.

1. Proposed Changes

We proposed to modify the existing network design requirements for the Pb surveillance monitoring network to achieve better understanding of ambient Pb air concentrations near Pb emission sources and to provide better information on exposure to Pb in large urban areas. We proposed that monitoring be presumptively required at sites near sources that have Pb emissions (as identified in the latest National Emissions Inventory (NEI) or by other scientifically justifiable methods and data) that exceed a Pb ''emission threshold''. This monitoring requirement would apply not only to existing industrial sources of Pb, but also to fugitive sources of Pb (e.g., mine tailing piles, closed industrial facilities) and airports where leaded aviation gasoline is used. In this context, the ''emission threshold'' was intended to be the lowest amount of Pb emissions per year for a source that may reasonably be expected to result in ambient air concentrations at a nearby monitoring site in excess of the proposed Pb NAAQS (as discussed later, based on reasonable worst case scenarios). We conducted an analysis to estimate the appropriate emission threshold (Cavender 2008a) which is available in the docket for this rulemaking. Using the results from this analysis, we proposed that the emission threshold be set in the range of 200 kg–600 kg per year total Pb emissions (including point, area, and fugitive emissions and including Pb in all sizes of PM), corresponding to the proposed range of levels for the Pb NAAQS, with the final selection of the threshold to be dependent on the final level for the NAAQS.

We recognized that a number of factors influence the actual impact a source of Pb has on ambient Pb concentrations (e.g., local meteorology, emission release characteristics, and terrain). Accordingly, we also proposed to allow monitoring agencies to petition the EPA Regional Administrator to waive the requirement to monitor near a source that emits less than 1000 kilograms per year where it can be shown that ambient air concentrations at that site are not expected to exceed 50 percent of the NAAQS during a three-year period (through modeling, historical monitoring data, or other means). We proposed that for facilities identified as emitting more than 1000 kilograms per year in the NEI, a waiver would only be provided for those sites at which it could be demonstrated that actual emissions are less than the emission threshold.

We proposed that source-oriented monitors be located at locations of maximum impact classified primarily as microscale monitors representative of small hot-spot areas adjacent or nearly adjacent to facility fence-lines. We also indicated that source-oriented monitors may be located at locations of maximum impact but which are representative of larger areas and classified as middle scale. Additionally we sought comments on the appropriateness of requiring monitors near Pb sources.

We also proposed a small network of non-source-oriented monitors in urban areas in addition to the source-oriented monitors discussed above, in order to gather additional information on the general population exposure to Pb in ambient air. While it is expected that these non-source-oriented monitors will show lower concentrations than source-oriented monitors, data from these non-source-oriented monitors will be helpful in better characterizing population exposures to ambient air-related Pb and may assist in determining nonattainment boundaries. We proposed to require one non-source-oriented monitor in each Core Based Statistical Area (CBSA, as defined by the Office of Management and Budget [109]) with a population of 1,000,000 people or more as determined in the most recent census estimates. Based on the most current census estimates, 52 CBSAs would be required to have non-source-oriented population monitors (see *http://www.census.gov/popest/metro/index.html* for the latest census estimates.)

We noted in our proposal that monitoring agencies would need to install new Pb monitoring sites as a result of the proposed revisions to the Pb monitoring requirements. We estimated that the size of the required Pb network would range between approximately 160 and 500 sites, depending on the level of the final standard. If the size of the final network is on the order of 500 sites, we proposed to allow monitoring agencies to stagger the installation of newly required sites over two years, with at least half the newly required Pb monitoring sites being installed and operating by January 1, 2010 and the remaining newly required monitoring sites installed and operating by January 1, 2011. As proposed, monitors near the highest Pb emitting sources would need to be installed in the first year, with monitors near the lower Pb emitting sources and non-source-oriented monitors being installed in the second year. We also proposed to allow monitoring agencies one year following the release of updates to the NEI or an update to the census to add new monitors if these updates would trigger new monitoring requirements.

We also proposed to allow States to use Pb-PM_{10} monitors to meet the network design requirements if our proposed use of scaled Pb-PM_{10} data was adopted in the final rule.

2. Comments on Network Design

We received several comments on the proposed network design requirements. These comments and our responses are broken down into the following categories: source-oriented monitoring, non-source-oriented monitoring, roadway monitoring, the use of Pb-PM_{10} samplers, and the required timeline for installing newly required monitors.

a. Source-oriented monitoring

We received several comments supporting the need for monitoring near Pb sources. Alternatively, one commenter suggested that near source monitoring is not necessary because ''the EPA and the State already know where and what the problems are'' and ''EPA should * * * develop control standards to deal with the problem * * *'' We note individual sources do not violate a NAAQS but that under the CAA a primary method to achieve control of emissions at sources contributing to an exceedence of the NAAQS is the State Implementation Plan (SIP). We expect the highest concentrations of Pb to be near sources of Pb due to its dispersion characteristic. Monitoring data are important evidence used to designate areas as non-attainment of the NAAQS. Thus, monitoring near Pb sources is needed to properly designate areas that violate or contribute to air quality in a nearby area that does not meet the Pb NAAQS.

We received a comment that the methods used in developing the emission thresholds estimated ambient impacts over different averaging periods, and that the emission thresholds should be recalculated for all methods using the final averaging period. We recognized this issue in our memorandum documenting the analysis (Cavender, 2008a), and we have recalculated the estimate of the lowest Pb emission rate that under reasonable worst-case conditions could lead to Pb concentrations exceeding the NAAQS, based on the final level and form of the standard (Cavender, 2008b).

We also received comments on the approach used in developing the

[109] For the complete definition of CBSA refer to: *http://www.census.gov/population/www/estimates/aboutmetro.html.*

proposed emission thresholds that would trigger consideration of the placement of a monitoring site near a Pb source. Commenters expressed concerns that the approach overestimated the potential impact of Pb sources, and would result in either unnecessary burden on monitoring agencies or worse yet, monitoring agencies would install and operate monitors at sources that had little to no potential to exceed the NAAQS. Several commenters suggested various alternative levels, including a threshold of 1 ton or higher, basing their recommendations on concerns such as the reliability of data in the NEI. Other commenters suggested that EPA was in the best position to determine which sources had the potential to exceed the NAAQS.

We note that the approach used in developing the emission threshold in the proposal was intended to represent a reasonable worst case scenario. As such, we recognize that many Pb sources which emit at or above the proposed emission threshold will have Pb impacts that are below the Pb NAAQS. To account for this, we proposed to allow monitoring agencies to request monitoring waivers if they could demonstrate that facilities would not contribute to a Pb impact of greater than 50 percent of the NAAQS. However, upon further consideration, we agree that by basing the threshold on these worse case condtions we will be placing an unnecessary burden on monitoring agencies to evaluate or monitor around sources that may not have a significant potential to exceed the NAAQS. As a result, we are finalizing changes to our approach for requiring source-oriented monitors. We are including a requirement that monitoring agencies conduct monitoring taking into account sources that are expected to exceed or shown to have contributed to a maximum concentration that exceeded the NAAQS, the potential for population exposure, and logistics. In addition, specifically we are requiring monitoring agencies to conduct monitoring at sources which emit Pb at a rate of 1.0 or more tons per year. This emissions rate corresponds to two times the estimate of the lowest Pb emission rate that under reasonable worst-case conditions could lead to Pb concentrations exceeding the NAAQS. This recognizes the thresholds used in the proposal represented reasonable worst case scenarios, and that a more appropriate approach to balance the factors important in designing a network is to use a higher threshold that is more likely to clearly identify sources that would contribute to exceedences of the NAAQS. In addition, the State, and the Agency working together will identify what additional sources should be taken into account because they are expected to or have been shown to contribute to maximum concentrations that contribute to exceedences.

To account for the other sources that may contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, we are retaining the authority granted to the EPA Regional Administrator in the existing monitoring requirements to require monitoring ''where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied.'' We believe that these final monitoring requirements are adequate to ensure that monitoring will be conducted respecting facilities that have the potential to exceed the NAAQS without placing undue burden on monitoring agencies.

We received several comments supporting the need for monitoring waivers, and one comment that did not support waivers. Those in favor of the waivers pointed out that, as discussed above, many Pb sources will result in much lower Pb impacts than the ''worst case'' Pb source. They argued that the states need flexibility in meeting the source-oriented monitoring requirements, and agreed that it is appropriate to focus on sites near those Pb sources with the greater potential to result in Pb concentrations that exceed the Pb NAAQS. The commenter who cautioned against the allowance of monitoring waivers expressed concerns that modeling results are not exact and this uncertainty could result in waivers being granted when actual Pb concentrations could exceed the NAAQS. We took the uncertainty of modeled results into account when proposing to limit waivers to situations where the modeled data indicated maximum concentrations would be 50 percent of the NAAQS, rather than at 100 percent of the NAAQS, and we believe this provides a sufficiently protective approach to account for uncertainty in modeling and other assessments estimating a Pb source's expected impacts.

We received comments questioning the need to restrict the provision of waivers to sites near sources emitting less than 1000 kg/yr. We agree it is possible for sources greater than 1000 kg/yr to have an impact less than 50 percent of the NAAQS under certain conditions. We also acknowledge the need for flexibility in implementing the Pb NAAQS monitoring network. As such, we have reconsidered our proposed restriction limiting waivers to those for sources emitting less than 1000 kg/yr, and we are not finalizing a restriction on the size of sources near sites eligible for a waiver from the source-oriented monitoring requirement.

We received comments on relying on the National Emission Inventory (NEI) to identify Pb sources with emissions greater than the emission threshold. In general, several commenters said better data should be used to identify Pb sources emitting above the proposed emission threshold. Several commenters expressed concerns with the accuracy of the NEI, and recommended allowing states to use ''the best available information'' on emissions from Pb sources. Some commenters pointed to differences in Pb emissions data reported in the Toxics Release Inventory and the NEI as evidence that the NEI was inaccurate. One commenter said current practices to reduce toxic emissions are not reflected in the NEI and wanted the opportunity to update the information. Commenters said EPA should correct the errors in the NEI or allow states to submit revised local data that more accurately reflect Pb emissions before emissions inventory data are used to determine which sources exceed the threshold.

We agree that the most current Pb emissions information should be used when making final decisions about which sources exceed the emission threshold. This may include datasets that could include sources not contained in the NEI. We acknowledge that many of the NEI emission estimates likely would be improved with more site specific data (e.g., emissions test data). We have added the phrase ''or other scientifically justifiable methods and data'' to the monitoring requirements to clarify that NEI emissions estimates are not the only emission estimates that can be used to estimate emissions.

We received comments that the proposed source-oriented monitoring requirements did not address situations where multiple sources contribute to Pb concentrations at one location. Our proposed waiver requirements do take into account the impacts from multiple sources. The proposed language stated that waivers could only be granted for source-oriented sites that did not ''contribute to a maximum Pb concentration in ambient air in excess of 50 percent of the NAAQS''. We recognize that exceedances of the standard may be caused by emissions from a number of smaller sources none of which would cause a violation in

isolation, but we expect it is unlikely that violations would occur when all of the sources in an area are below the emissions threshold due to the rapid decrease in Pb concentrations with distance from a Pb source. However, the purposes of the monitoring network would be undermined if multiple sources in a single area were able to receive waivers, with the result that no monitor was required even though Pb concentrations in the area were in excess of 50 percent of the standard. Accordingly, EPA expects that Regional Administrators, in deciding whether to grant waivers, will take into account whether other waivers have been granted or sought for sources in the same area, and whether the cumulative emissions of the sources in the area warrant at least one monitor being sited.

Several monitoring agencies expressed concern about the need for flexibility in implementing the source-oriented monitoring requirements. We believe that the proposed rule provides significant flexibility to monitoring agencies for the implementation of the monitoring requirements. One area where we believe it is appropriate to provide additional flexibility is for situations where multiple sources above the emission threshold contribute to a single maximum impact. A strict reading of the proposed source-oriented monitoring requirement could be that monitoring agencies would be required to monitor each Pb source separately. This was not intended, and our existing monitoring guidance is clear that a single monitor can be used to monitor multiple sources where the maximum impact is influenced by multiple sources. Nonetheless, we believe it is appropriate to clarify this point in the rule language. As such, we are adding a clause to the source-oriented monitoring requirement that specifies that a single monitor can be used to monitor multiple Pb sources where they contribute to a single maximum impact.

We received two comments that source-oriented monitors should be located at the location of maximum estimated Pb concentration without consideration for the potential for population exposure, and six comments that source-oriented monitors should be located in an area where population exposure occurs. In their comments on the proposed rule, one commenter argued that monitors ''should be located in or around only those Pb point sources with a nearby population base'' because ''air Pb concentrations have regulatory importance largely in those areas where significant groups of children are exposed for considerable time periods.'' The commenter argued that as an example ''a rural road going by a lead mining facility is an unlikely place that children will spend considerable amounts of time'' and as such ''placing a monitoring site on such a road would have de minimis, if any, value.'' Another commenter suggested that ''monitors should be located near playgrounds, sports fields, long-established highways, and the like.''

Siting of required monitors at the expected maximum concentration in ambient air is consistent with how all NAAQS pollutants are monitored.[110] In considering the siting criteria for the required Pb source-oriented monitors, we recognize that Pb is a persistent, multimedia pollutant, such that deposited Pb from current emissions can contribute to human exposures over extended amounts of time. Also, Pb deposited in one area can be transported to another area by ''tracking'' from vehicle and foot traffic. In addition, unlike the case for other criteria pollutants, ingestion of deposited Pb is a major Pb exposure pathway. Given these complexities, it is appropriate to allow siting agencies to also consider the potential for population exposure in siting monitors near sources.

In our proposed rule, we recognized that there are reasons for not requiring monitoring at the location of expected maximum concentration such as logistical limitations (i.e., the location of expected maximum concentration occurs in the middle of a lake). In consideration of public comments on this issue and due to the complexities of Pb, we believe it is appropriate, in the final rule, to also allow states to consider the potential for population exposure as a factor (in addition to other factors such as logistical considerations) when siting required source-oriented monitors. Thus, we are including the potential for population exposure as a factor that monitoring agencies can consider when siting a maximum concentration source-oriented monitoring site required under part 58.

b. Non-source-oriented monitoring

We received a number of comments on our proposed non-source-oriented monitoring requirement. One state and several tribes commented that the proposed population limit would result in no required non-source-oriented monitors in low population states and tribal lands. One commenter expressed concerns that the population limit was too high, and would result in environmental justice concerns since many poor communities would not be monitored.

As stated in the proposed rule, it is unlikely that exceedences of the Pb NAAQS will occur at sites distant from Pb sources. As such, our non-source-oriented monitoring requirements satisfy monitoring objectives in addition to ensuring compliance with the Pb NAAQS. For the most part, these monitoring sites should be sited to represent neighborhood scale exposures. We are requiring non-source-oriented Pb monitors to provide additional information that will be useful in better characterizing air-related Pb exposures in neighborhoods. Sources affecting neighborhoods may include re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive sources of Pb. Non-source sites will also support the next Pb NAAQS review by providing additional information on the spatial variations in Pb concentrations between areas that are affected by sources to a significant degree and those that are not.

We believe it is most appropriate to focus the non-source monitoring requirements in large urban areas since high population locations are most used in health and epidemiological studies. We proposed to require one non-source-oriented monitor in each CBSA with a population of 1,000,000 or more based on the latest available census figures. That proposed requirement would have resulted in approximately 50 CBSAs required to have non-source Pb monitors. EPA notes the comments that the proposed population limit of 1,000,000 was too high, and may result in the lack of non-source-oriented monitors in smaller urban communities. Accordingly, we have decreased the population limit for requiring non-source monitors to CBSAs with a population of 500,000 people or more, thereby increasing the number of required non-source Pb monitors from approximately 50 to approximately 100 (based on 2007 population estimates from the Census Bureau).

We also note that these requirements are minimum monitoring requirements, and that state and tribal monitoring agencies may operate additional non-source-oriented monitors beyond the minimum number of required monitors. Data that meet the quality assurance requirements that are collected from non-required FRM or FEM monitors will also be used to determine compliance with the Pb NAAQS. Additionally, as

[110] Required $PM_{2.5}$ sites have additional criteria where monitoring sites are to represent community-wide air quality [40 CFR part 58, appendix D paragraph 4.7.1(b)] with at least one required site in a population-oriented area of expected maximum concentration.

described previously, source-oriented monitoring would be required in rural and small communities if a Pb source emitting 1 ton per year or more is present.

c. Roadway Monitoring

The majority of commenters agreed with our finding that the available data on Pb concentrations near roadways do not indicate the potential for exceedances of the proposed range of Pb NAAQS levels and requirements for monitors near roadways were not needed to ensure compliance with the NAAQS. However, one commenter argued that our finding that activity on roadways would not likely contribute to air Pb concentrations in exceedance of the proposed levels for the standard was based on data from monitors that did not represent the maximum impact from roadways.

While some of the monitors used in our analysis of air Pb impacts from activity on roadways may not represent the site of maximum impact, we believe they are representative of locations where roadway monitoring might be conducted. As we indicated in our proposal, these monitors indicate that Pb concentrations are slightly elevated near roadways, but do not occur at levels approaching the Pb NAAQS being finalized today. Nonetheless, we agree that more information on Pb concentrations near roadways would be valuable, and we encourage monitoring agencies to consider placing Pb monitors near population centers heavily impacted by roadways in some of the CBSAs required to install and operate non-source-oriented monitors to provide information for use in future NAAQS reviews. In addition, the EPA has research initiatives investigating Pb concentrations near roadways that will provide additional information that can be used in future NAAQS reviews.

d. Use of Pb-PM_{10} Monitors

Comments were received on the use of Pb-PM_{10} monitoring in lieu of required Pb-TSP under certain circumstances. Several commenters suggested an approach for the use of Pb-PM_{10} monitors as an alternative to the proposed use of scaling factors. Commenters suggested that Pb-PM_{10} monitoring would only be allowed in certain instances. Specifically, Pb-PM_{10} monitoring would be allowed where estimated Pb concentrations were predicted to be less than 50 percent of the NAAQS and where Pb in ultra-coarse particulate was expected to be low. These commenters also suggested that if at some point in the future the monitor were to show that Pb-PM_{10} concentrations exceeded 50 percent of the NAAQS, the monitoring agency would be required to replace the Pb-PM_{10} monitor with a Pb-TSP monitor.

We support this suggested approach, noting that it allows for the use of Pb-PM_{10} in areas where we do not expect Pb concentrations to exceed the Pb NAAQS without the burden and uncertainty associated with the development and use of site-specific scaling factors. As noted in section II.C.1, use of Pb-PM_{10} monitors in these locations offers the advantages of increased monitor precision and decreased spatial variation of Pb-PM_{10} concentrations, without raising the same concerns over a lack of protection against health risks from all particulate Pb emitted to the ambient air that support retention of Pb-TSP as the indicator.

However, we feel the combined requirements for allowing use of Pb-PM_{10} monitors only in areas where the concentration is expected to be less than 50% of the NAAQS and where Pb in ultra-coarse particles is expected to be low may be too restrictive, especially in light of the fact that a monitoring agency may request a waiver from monitoring altogether if the expected concentration is less than 50% of the NAAQS. We believe it is appropriate to allow Pb-PM_{10} in lieu of Pb-TSP where the maximum 3-month arithmetic mean Pb concentration is expected to be less than 0.10 $\mu g/m^3$ (i.e., two thirds of the NAAQS) and where sources are not expected to emit ultra-coarse Pb. By limiting the use of Pb-PM_{10} monitoring to locations where the Pb concentrations are less than 0.10 $\mu g/m^3$ on a 3-month arithmetic mean and where ultra-coarse Pb is expected to be low, we believe that the Pb-TSP concentrations will also be less than 100% of the NAAQS. Examples of locations where Pb-PM_{10} monitoring may be more representative of Pb-TSP levels than others are urban areas away from Pb sources (i.e., non-source-oriented monitoring locations), near airports, combustion sources, and other Pb sources which are expected to only emit Pb in the fine PM size fraction. Locations where it would not be appropriate to monitor using Pb-PM_{10} samplers include near smelters, roadways, and sources with significant fugitive dust emissions.

We are revising the proposed allowance for the use of Pb-PM_{10} monitors to allow Pb-PM_{10} monitors without the use of scaling factors for non-source-oriented monitors (unless existing data indicates maximum 3-month arithmetic mean Pb concentration has exceeded 0.10 $\mu g/m^3$ in the last three years) and for source-oriented monitors where maximum 3-month arithmetic mean Pb concentration is expected to be less than 0.10 $\mu g/m^3$ (based on modeling or historic data) and where ultra-coarse Pb is expected to be low. We are also requiring that a Pb-TSP monitor be required at the site if at some point in the future the Pb-PM_{10} monitor shows that the maximum 3-month arithmetic mean Pb-PM_{10} concentration was equal to or greater than 0.10 $\mu g/m^3$. Section IV.E of this preamble discusses how data from Pb-PM_{10} monitors will be used in comparison to the Pb NAAQS.

e. Required Timeline for Monitor Installation and Operation

We received several comments from monitoring agencies regarding the proposed timeline for monitor installation. Commenters supported the need for a staggered network deployment, especially if a large number of new monitors would be required. Two commenters argued that even the proposed two-year deployment would not provide enough time for monitoring agencies to site and install the number of monitors needed.

Based on the network design requirements being finalized with this action, we estimate that approximately 135 facilities emit Pb at levels over the ''emissions threshold'' of 1 ton per year and would result in required monitoring. We are also requiring urban areas with populations over 500,000 to site non-source-oriented monitors, thus another 101 monitors are required. Together the required source-oriented and non-source-oriented monitors are expected to total 236 monitors. Some of the existing 133 lead monitoring stations will be useful to support the required network, but other stations may need to move. We are estimating that approximately 90 of the existing stations are in locations that are of benefit to other monitoring objectives, even when well below the NAAQS (e.g., long-term trends or for use in a health study) and are not part of the minimum network requirements being finalized in today's action. Once the network is fully operational the 236 required stations plus an additional 90 stations in existing locations that are not required results in an expected network of 326 lead monitoring stations to adequately support characterization of lead across the country.

We believe it would be unrealistic to require monitoring agencies to site and install the required 240 new monitoring stations within one year, even if some of these are already in the right locations. However, we do believe it is reasonable to require monitoring

agencies to site and install half of these stations in one year with the remaining stations deployed in the following year. Accordingly, and as discussed further below, we are finalizing a two-year monitor deployment schedule for required monitoring.

3. Decisions on Network Design Requirements

We are finalizing new network design requirements for the Pb NAAQS monitoring network that differ from those proposed in the following aspects. The differences from the proposal reflect our consideration of the comments on the proposed network design requirements and consideration of the level, form, and averaging time for the final NAAQS being promulgated today.

We are adding a requirement that monitoring agencies conduct ambient air Pb monitoring taking into account Pb sources which are expected to or have been shown to contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, the potential for population exposure, and logistics. At a minimum, there must be one source-oriented SLAMS site located to measure the maximum Pb concentration in ambient air resulting from each Pb source which emits 1.0 or more tons per year based on either the most recent NEI or other scientifically justifiable methods and data (such as improved emissions factors or site-specific data). We are maintaining the existing authority for the EPA Regional Administrator to require additional monitoring where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied. In addition, we are adding a clause to the source-oriented monitoring requirement to clarify that a single monitor may be used to monitor multiple Pb sources when the sources contribute to a single maximum Pb concentration.

In addition, monitoring agencies may consider the potential for population exposure when siting source-oriented monitors. While this change does not restrict monitoring agencies from monitoring at any location meeting the definition of ambient air, this provision allows monitoring agencies to consider the potential for population exposure when siting the required source-oriented monitors at the maximum Pb concentration.

We are removing the proposed restriction that waivers may only be granted for sites near sources emitting less than 1000 kg/yr. The EPA Regional Administrator may approve waivers for the source-oriented monitoring requirement for any site where the monitoring agency demonstrates that the emissions from the source will not contribute to a Pb-TSP concentration greater than 50 percent of the final NAAQS (based on historic data, monitoring data, or other means).

We are requiring one non-source-oriented monitor in every CBSA with a population of 500,000 people or more. In addition, we are requiring these monitors be placed in neighborhoods within urban areas impacted by re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive dust sources of Pb.

Monitoring agencies may use Pb-PM_{10} monitors to meet the non-source-oriented monitoring requirements tied to CBSA population provided that historical monitoring does not indicate Pb-TSP or Pb-PM_{10} concentrations greater than an arithmetic 3-month mean of 0.10 $\mu g/m^3$, and to meet the source-oriented monitoring requirements where Pb concentrations are expected (based on historic data, monitoring data, or other means) to be less than 0.10 $\mu g/m^3$ on an arithmetic 3-month mean, and ultra-coarse Pb is expected to be low. However, monitoring agencies are required to begin monitoring for Pb-TSP within six months of a measured Pb-PM_{10} arithmetic 3-month mean concentration of 0.10 $\mu g/m^3$ or more. For example, if a Pb-PM_{10} monitoring site measures an arithmetic 3-month mean concentration of 0.10 $\mu g/m^3$ or more for the period March–May 2011, the responsible monitoring agency would be required to install and begin operation of a Pb-TSP monitor at the site no later than December 1, 2011.

We are allowing monitoring agencies to stagger installation of any newly required monitors over a two-year period. Each monitoring agency is required to install and operate the required source-oriented monitors by January 1, 2010. The non-source-oriented monitors are required to be installed and operated by January 1, 2011. The annual monitoring plan due July 1, 2009 must describe the planned monitoring that will begin by January 1, 2010, and the plan due July 1, 2010 must describe the planned monitoring that will begin by January 1, 2011.

C. Sampling Frequency

We proposed to maintain the 1-in-6 day sampling frequency if the final averaging time for the NAAQS standard was based on a quarterly average. We did not receive any comments on our proposed sampling frequency for a NAAQS based on a quarterly average. While the final NAAQS is based on a moving 3-month average rather than a quarterly average, the statistical and practical monitoring considerations are the same. As such, we are maintaining the current 1-in-6 day minimum sampling frequency as proposed (i.e., monitoring agencies will be required to collect at least one 24-hour Pb sample every six days).

D. Monitoring for the Secondary Standard

We did not propose any specific additional monitoring requirements for the secondary standard because based on the available data, we do not expect exceedances of either the primary or the secondary NAAQS away from the point sources that will be addressed by the monitoring requirements already described. We also noted that the Pb-$PM_{2.5}$ data collected as part of the Interagency Monitoring of Protected Visual Environments (IMPROVE) program provide useful information on Pb concentrations in rural areas that can be used to track trends in ambient air Pb concentrations in rural areas including important ecosystems. We received one comment supporting our proposed reliance on the IMPROVE network Pb-$PM_{2.5}$ data. We did not receive any other comments on additional monitoring needs to support the secondary Pb NAAQS. Thus, we are not finalizing any additional requirements for Pb monitoring specifically for the secondary Pb NAAQS.

E. Other Monitoring Regulation Changes

We are finalizing two other proposed changes to the monitoring requirements for Pb, and making one editorial revision for ease of reference. We are changing the reporting requirements to require the reporting of average pressure and temperature for each Pb sample collected. We are also removing Pb from the list of criteria pollutants where data from special purpose monitors can be excluded from consideration for designations. The proposed changes, comments received, and final amendments are described in the following paragraphs.

1. Reporting of Average Pressure and Temperature

We proposed revisions to 40 CFR 58.16(a) to add a requirement that the monitoring agency report the average pressure and temperature during the time of sampling for both Pb-TSP monitoring and Pb-PM_{10} monitoring. We did not receive any comments on this

proposed requirement. As such, we are finalizing this requirement as proposed. Monitoring agencies may use site specific meteorological measurements generated by on-site equipment (meteorological instruments, or sampler generated), a representative nearby monitoring station, or measurements from the nearest airport reporting ambient pressure and temperature.

2. Special Purpose Monitoring

We proposed to revise 40 CFR 58.20(e) by removing the specific reference to Pb in the rule language. We proposed to make this change because the form of the proposed Pb NAAQS would allow a non-attainment finding to be based on as little as 3-months of data which would have to be considered during mandatory designations. We did not receive any comments on this proposed revision to the special purpose monitoring requirements. As such, we are finalizing the revision to 40 CFR Section 58.20(e) as proposed.

VI. Implementation Considerations

This section of the final rule discusses the specific CAA requirements related to implementation of the revised Pb NAAQS based on the structure outlined in the CAA, existing rules, existing guidance, and in some cases revised guidance.

The CAA assigns important roles to EPA, states, and tribal governments in implementing NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain state measures necessary to achieve the air quality standards in each area. EPA provides assistance to states and tribes by providing technical tools, assistance, and guidance, including information on the potential control measures.

A SIP is the compilation of regulations and control programs that a state uses to carry out its responsibilities under the CAA, including the attainment, maintenance, and enforcement of the NAAQS. States use the SIP development process to identify the emissions sources that contribute to the nonattainment problem in a particular area, and to select the emissions reduction measures most appropriate for the particular area in question. Under the CAA, SIPs must ensure that areas reach attainment as expeditiously as practicable, but by no later than the statutory attainment date that is set for the area.

The EPA's analysis of the available Pb monitoring data suggests that a large percentage of recent Pb ambient air concentrations in excess of 0.15 $\mu g/m^3$ have occurred in locations with active industrial sources of lead emissions. Accordingly, we anticipate that many areas may be able to attain the revised NAAQS by implementing air pollution control measures on lead emitting industrial sources only. These controls could include measures such as particulate matter fabric filter control devices and industrial fugitive dust control measures applied in plant buildings and on plant grounds. However, it may become necessary in some areas to also implement controls on non-industrial, or former industrial, type sources. Based on these considerations, EPA believes that the regulations and guidance currently being used to implement the pre-existing Pb NAAQS are still appropriate to implement the revised Pb NAAQS with modifications in some cases.

The regulations and guidance which address the implementation of the pre-existing NAAQS for Pb are mainly provided in the following documents: (1) ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'', 57 FR 13549, April 16, 1992, (2) ''State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'', 58 FR 67748, December 22, 1993, and (3) regulations listed at 40 CFR 51.117. These documents address requirements such as designating areas, setting nonattainment area boundaries, promulgating area classifications, nonattainment area SIP requirements such as Reasonably Available Control Measures (RACM), Reasonably Available Control Technology (RACT), New Source Review (NSR), Prevention of Significant Deterioration (PSD), and emissions inventory requirements. The EPA believes that the existing guidance and regulations are sufficient to implement the revised Pb NAAQS at this time. As discussed below, EPA is finalizing some changes to the existing guidance and regulations, and EPA will, as appropriate, review, and revise or update these policies, guidance, and regulations to ensure effective implementation of the Pb NAAQS.

Several commenters submitted comments stating that the usual agency practice for revising the NAAQS has been to first promulgate a rule setting the health and welfare based standards, and then to promulgate a rule that addresses the numerous implementation issues relating to the NAAQS. These commenters stated that the lead NAAQS proposal, however, combines these two rulemakings into one compressed rule. Commenters stated that they theoretically believe that this two-in-one rule approach could benefit states and localities by preventing the types of delays that have been encountered with the implementation of other pollutants. The commenters, however, stated that they believe that the lead NAAQS implementation provisions in the proposed rule are insufficient to give state and local agencies adequate guidance to implement the revised standard. Commenters further stated that they believe that EPA should particularly update lead control strategy and emissions inventory guidance documents to account for the change to the level of the standard.

As stated in the proposed rule, EPA believes that the regulations and guidance currently being used to implement the pre-existing Pb NAAQS are generally still appropriate to address the issues required to begin implementing the revised Pb NAAQS. As discussed in the proposal, EPA is revising the emission inventory requirements of 40 CFR 51.117(e)(1). In some areas, as discussed below, EPA is providing additional guidance in response to comments. The EPA believes that these policies, guidance and regulations should be used by states, local, and Tribal governments as a basis for implementing the revised Pb NAAQS. Also, as stated in the proposed rule, EPA will as appropriate, further review and revise or update these policies, guidance, and regulations in the future to ensure that states, local, and Tribal governments have the appropriate information necessary to fully implement the revised Pb NAAQS in a timely manner.

As discussed below, the EPA is generally finalizing the guidance concerning the implementation of the revised Pb NAAQS consistent with the proposed rule.

A. Designations for the Lead NAAQS

1. Proposal

As discussed in the proposed rule, after EPA establishes or revises a primary and/or secondary NAAQS, the CAA requires EPA and the states to begin taking steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. The CAA defines EPA's authority to designate areas that do not meet a new or revised NAAQS. Section 107(d)(1) provides that ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under

section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the state'' that designates those areas as nonattainment, attainment, or unclassifiable. Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended by up to one year in the event the Administrator has insufficient information to promulgate the designations.'' The term ''promulgation'' has been interpreted by the courts to mean the signature and dissemination of a rule.[111] By no later than 120 days prior to promulgating final designations, EPA is required to notify states or Tribes of any intended modifications to their boundaries as EPA may deem necessary. States and Tribes then have an opportunity to comment on EPA's tentative decision. It should be noted that, whether or not a state or a Tribe provides a recommendation, EPA must promulgate the designation that it deems appropriate.

In the proposal, EPA indicated that Governors and tribal leaders would be required to submit their initial designation recommendations to EPA no later than September 2009, and the initial designation of areas for the new Pb NAAQS would occur no later than September 2010, although that date may be extended by up to one year under the CAA (or no later than September 2011) if EPA has insufficient information to promulgate the designations. These dates were based on the court-ordered schedule in effect at the time of proposal, which required a final rule to be signed no later than September 15, 2008. The court-ordered schedule was subsequently amended to require a notice of final rulemaking to be signed no later than October 15, 2008.

In the proposed rule, EPA also discussed issues related to possible schedules for designations, and EPA took comment on issues related to the anticipated designation schedule. The proposal identified two ''key considerations'' in establishing a schedule for designations: ''(1) The advantages of promulgating all designations at the same time; and (2) the availability of a monitoring network and sufficient monitoring data to identify areas that may be violating the NAAQS'' (73 FR 29267). The EPA then stated its view that ''there are important advantages to promulgating designations for all areas at the same time'' and expressed its intention to do so.

The proposal also discussed EPA's belief that the existing Pb monitoring network is not adequate to evaluate attainment of the revised Pb NAAQS at locations consistent with EPA's proposed new monitoring network siting criteria and data collection requirements. These new requirements would result in a more strategically targeted network that would begin operation by January 1, 2010. The proposal pointed out that taking the additional year provided under section 107(d)(1)(B)(i) of the CAA (which would allow up to 3 years to promulgate initial designations following the promulgation of a new or revised NAAQS) would allow the first year of data from the new monitoring network to be available. The proposal also stated that, due to the updated monitoring network design requirements, this additional data would be of significant benefit for designating areas for the new NAAQS.

Accordingly, the proposal identified an initial designation schedule under which states (and Tribes) would be required to submit designation recommendations to EPA no later than one year following promulgation of the new NAAQS. States would be able to consider ambient data collected with the existing network FRM and FEM samplers through the end of calendar year 2008 when formulating their recommendations. The proposal further indicated that if, as EPA anticipated, EPA needed an additional year to make designations due to insufficient information, EPA would have access to Pb air quality monitoring data from calendar year 2010, which state monitoring officials have certified as being complete and accurate, since the deadline for such certification is May 1, 2011. Under this schedule, EPA would be able to consider data from calendar years 2008–2010 in formulating its proposed revisions, if any, to the designations recommended by states and Tribes. States and Tribes would then have an opportunity to comment on EPA's proposed modifications, if any, prior to the promulgation of designations by Fall 2011. The EPA solicited comment on whether EPA has the authority to determine in this final rule that three years would be necessary to make designations. The EPA also solicited comment on making designations within two years from promulgation of a revised NAAQS.

2. Comments and Responses

Several commenters suggested that EPA should require that states with current nonattainment or maintenance areas submit designation recommendations for those counties or Metropolitan Statistical Areas (MSAs) with nonattainment or maintenance areas within 120 days of promulgation of the rule.

Section 107(d)(1)(A) provides that States shall submit recommendations for areas to be designated attainment, nonattainment, and unclassifiable ''[b]y such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109.'' EPA's consistent practice in revising NAAQS has been to allow states a year to prepare their lists of designations, and the proposal likewise indicated EPA's intent to allow a year for states to prepare their recommendations. It is often true that when a standard is made more stringent there will be existing nonattainment and maintenance areas that may be expected to be nonattainment for the new standard as well. Furthermore, EPA notes that the most recent three years of available monitoring data for East Helena, MT, one of the two current nonattainment areas, showed no violations of the current standard, although the monitors were shut down in December 2001 following the shutdown of the large stationary source of lead emissions there. The EPA also notes that preparing designation recommendations is a complex task, and the magnitude of the reduction in the Pb NAAQS, and the long interval since the last revision to the standard is likely to add to the difficulty for states.

Thus, while EPA considers the increased stringency of the standard to be relevant to the question of when states should submit designation recommendations, EPA does not believe that under the current circumstances it would be reasonable to require states to submit a list of areas to be designated attainment, nonattainment, or unclassifiable sooner than one year following promulgation year.

Therefore, pursuant to section 107(d)(1)(A), states shall, and Tribes may, provide area designation recommendations to EPA no later than October 15, 2009.[112] In some areas, EPA

[111] *American Petroleum Institute* v. *Costle,* 609 F.2d 20 (D.C. Cir. 1979).

[112] Under the CAA and the Tribal Authority Rule (TAR), eligible Indian Tribes may develop and submit Tribal Implementation Plans (TIPs) for EPA approval, to administer requirements under the CAA on their reservations and in nonreservation

Continued

anticipates that state and Tribal officials will be able to base their recommendations on existing monitoring data, and can therefore identify an area as ''attainment'' or ''nonattainment.'' EPA also anticipates that there will be other areas where state and Tribal officials will not have sufficient information to make such a determination. State and Tribal officials are advised to identify such areas as ''unclassifiable.'' For these areas EPA may wait until sufficient ambient air quality data from the newly deployed Pb monitoring network are available to take final action on the state and Tribal recommendations.

Several commenters stated that EPA should promulgate designations for the revised Pb NAAQS within the 2 year period provided in the CAA. Commenters further stated that they do not understand why EPA needs to take an additional year beyond the two years provided under the CAA to do the designations. In addition, the commenters stated that they believe EPA does not have the authority to take the additional year (i.e., the 3rd year provided under section 107(d)(1)(B)(i) of the CAA) to do designations for the Pb NAAQS because sufficient monitoring data is available to do the designations within 2 years of promulgation of the NAAQS.

Other commenters stated that they agree with EPA that, given that the current monitoring network for the Pb NAAQS is insufficient to base designations on for the new NAAQS, EPA should not promulgate designations until there is sufficient data from the new monitoring network.

Section 107(d)(1)(B)(i) provides that the Administrator shall promulgate the designations of all areas as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended by up to one year in the event the Administrator has insufficient information to promulgate the designations.

After considering the comments, and recognizing that in some locations there may be monitoring data sufficient to determine whether or not the area is attaining the standard, EPA now believes that the benefits of identifying nonattainment areas as soon as possible, in some areas as discussed shortly below, outweigh the potential administrative benefits of designating all areas at the same time.

At the same time, EPA continues to believe that the current monitoring network is inadequate for making designations in many, if not most, areas of the country, and agrees with those commenters who stated that it would be preferable to wait until additional monitoring data was available for those areas than to proceed to designate areas based only on data from the current insufficient monitoring network. The EPA notes that any delay in designations beyond two years would be based on the lack of monitoring data (and the expectation that additional monitoring data would be available if designations were delayed) and would not be based on staffing and other non-data resource issues.

Accordingly, EPA believes that the most appropriate approach to designations for the Pb NAAQS is for EPA to complete final designations as expeditiously as possible, and to recognize that ''as expeditiously as possible'' may result in making nonattainment designations at different times for different areas. In some areas, EPA expects that it will be possible to do designations within two years based on currently available monitoring data. In other areas, EPA expects that taking the additional year will prove necessary in order to collect the necessary monitoring data before making designations.

3. Final

After considering the comments and for the reasons discussed above, EPA no longer plans to make all designations, and particularly all nonattainment designations, at the same time. The EPA intends to make designations as expeditiously as possible in areas where monitoring data is currently sufficient, or will be sufficient in the immediate future, to accurately characterize the areas as either not attaining or attaining the new Pb NAAQS. In some cases this will be possible as expeditiously as practicable, but no later than two years following promulgation of the final rule. In other cases this will not be possible until additional data are collected from the newly deployed monitoring network, and may take up to three years.

B. Lead Nonattainment Area Boundaries

1. Proposal

The process for initially designating areas following the promulgation of a new or revised NAAQS is prescribed in section 107(d)(1) of the CAA. This section of the CAA provides each state Governor an opportunity to recommend initial designations of attainment, nonattainment, or unclassifiable for each area in the state. Section 107(d)(1) of the CAA also directs the state to provide the appropriate boundaries to EPA for each area of the state, and provides that EPA may make modifications to the boundaries submitted by the state as it deems necessary. A lead nonattainment area must consist of that area that does not meet (or contributes to ambient air quality in a nearby area that does not meet) the Pb NAAQS. Thus, a key factor in setting boundaries for nonattainment areas is determining the geographic extent of nearby source areas contributing to the nonattainment problem. For each monitor or group of monitors that exceed a standard, nonattainment boundaries must be set that include a sufficiently large enough area to include both the area judged to be violating the standard as well as the source areas that are determined to be contributing to these violations.

Historically, Pb NAAQS violations have been the result of lead emissions from large stationary sources and mobile sources that burn lead-based fuels. In some locations, a limited number of area sources have also been determined to have contributed to violations. Since lead has been successfully phased out of motor vehicle gasoline, these sources are no longer a significant source of ambient lead concentrations. At the revised standard level, EPA expects stationary sources to be the primary contributor to violations of the NAAQS. However, it is possible that fugitive dust emissions from area sources containing deposited lead will also contribute to violations of the revised Pb NAAQS. The location and dispersion characteristics of these sources of ambient lead concentrations are important factors in determining nonattainment area boundaries.

In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. This presumption was also EPA's recommendation for defining the nonattainment boundaries for the 1978 Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). In the proposed rule, EPA also requested comment on an option to presumptively define the nonattainment boundary using the OMB-defined Metropolitan Statistical Area (MSA) associated with

areas under their jurisdiction. However, Tribes are not required to develop TIPs or otherwise implement relevant programs under the CAA. In cases where a Tribal air quality agency has implemented an air quality monitoring network which is affected by Pb emissions, the criteria and procedures identified in this rule may be applied for regulatory purposes. Certain Tribes may implement all relevant components of an air quality program for purposes of meeting the various requirements of this rule.

the violating monitor(s). This presumption was used historically, by the CAA requirement, for the 1-hr ozone and CO NAAQS nonattainment boundaries, and was also recommended by EPA as the appropriate presumption for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS nonattainment boundaries. In the proposed rule we stated that under either option, the state and EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive boundary. The factors relevant to such an analysis are described below.

For the proposed Pb NAAQS, EPA recommended that nonattainment area boundaries that deviate from presumptive county boundaries should be supported by an assessment of several factors, which are discussed below. The factors for determining nonattainment area boundaries for the Pb NAAQS under this recommendation closely resemble the factors identified in recent EPA guidance for the 1997 8-hour ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS nonattainment area boundaries. For this particular option of the proposal, EPA would consider the following factors in assessing whether to exclude portions of a county and whether to include additional nearby areas outside the county as part of the designated nonattainment area:

- Emissions in areas potentially included versus excluded from the nonattainment area.
- Air quality in potentially included versus excluded areas.
- Population density and degree of urbanization including commercial development in included versus excluded areas.
- Expected growth (including extent, pattern and rate of growth).
- Meteorology (weather/transport patterns).
- Geography/topography (mountain ranges or other air basin boundaries).
- Jurisdictional boundaries (e.g., counties, air districts, reservations, etc.).
- Level of control of emission sources.

The proposal indicated that analyses of these factors may suggest nonattainment area boundaries that are either larger or smaller than the county boundary. A demonstration supporting the designation of boundaries that are less than the full county would be required to show both that violation(s) are not occurring in the excluded portions of the county and that the excluded portions are not source areas that contribute to the observed violations. Recommendations to designate a nonattainment area larger than the county should also be based on an analysis of these factors. The proposal stated that EPA would consider these factors as well in evaluating state and Tribal recommendations and assessing whether any modifications are appropriate.

Under previous Pb implementation guidance, EPA advised that Governors could choose to recommend lead nonattainment boundaries by using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) Qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling. These techniques are more fully described in ''Procedures for Estimating Probability of Nonattainment of a PM_{10} NAAQS Using Total Suspended Particulate or PM_{10} Data,'' December 1986 (see 57 FR 13549). In the proposed rule, EPA solicited comments on the use of these factors and modeling techniques, and other approaches, for adjusting county boundaries in designating nonattainment areas.

2. Comments and Responses

Several commenters submitted comments stating that the nonattainment boundaries should be limited to the smallest political boundary that possesses an ambient monitor-based design value above the standard, unless subsequent analyses demonstrate that the boundaries should be larger or smaller. Commenters also stated that because lead does not transport over long distances, monitoring data from upwind and downwind sites illustrate that violations of the lead NAAQS are most commonly isolated within a specific geographic area in close proximity to a major source.

The EPA agrees with the commenter that lead emissions do not generally transport over long distances (as compared, e.g., to fine particulate matter). In the proposed rule, EPA proposed to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. In the proposed rule, EPA also stated that, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the NAAQS, although we also believe that nearby area sources may also contribute to concentrations of lead emissions that may affect a violating monitor. In light of the possibility that a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS, EPA believes that adopting the county boundary as the presumptive boundaries for lead nonattainment areas is appropriate. However, as stated in the proposed rule, a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive county boundary. In situations where a single source, rather than multiple sources, is causing a NAAQS violation, the EPA believes that a state may well be able to use area-specific analyses to identify whether a nonattainment area that is smaller than the county boundary is appropriate.

Several commenters stated that EPA should use the MSA as the presumptive boundary for designating areas for the Pb NAAQS in order for a broader range of source emissions to be taken into consideration when the state develops its SIP for the nonattainment area.

As stated previously, at the revised level of the standard, EPA expects stationary sources to be the primary contributor to violations of the Pb NAAQS, although we also expect that in some areas a number of smaller sources may collectively contribute to concentrations in excess of the NAAQS. MSAs are frequently composed of several counties. Recognizing that lead emissions, particularly ultracoarse particles, deposit relatively short distances from the proximity of their initial source, EPA believes that adopting the county boundary surrounding a violating monitor as the presumptive boundary for any given lead nonattainment area is more appropriate than presuming the larger MSA boundary. Furthermore, as stated in the proposed rule (and the previous response), a state, Tribe, or EPA may conduct additional area-specific analyses that could lead to the boundary for an area either being increased or decreased from the presumptive boundary. Thus, where it appears that emissions from one or more sources are contributing to nonattainment throughout an MSA, the site-specific analysis may result in the boundaries of the nonattainment area overlapping with those of the MSA.

3. Final

The EPA is finalizing the option to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard as proposed.

This presumption was also EPA's recommendation for defining the nonattainment boundaries for the pre-existing Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). As a part of the county boundary presumption for nonattainment areas, the state and/or EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive county boundary. The EPA is also finalizing the factors relevant to such an analysis as described in the proposed rule because we believe that they will allow for both the State as well as EPA in some cases to define better the appropriate boundaries for an area. The state may, in addition to submitting recommendations for boundaries based on the factor analysis, also choose to recommend lead nonattainment boundaries using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) Qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling, as described more fully in ''Procedures for Estimating Probability of Nonattainment of a PM_{10} NAAQS Using Total Suspended Particulate or PM_{10} Data,'' December 1986 (see 57 FR 13549).

C. Classifications

1. Proposal

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purpose of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify lead nonattainment areas, but is not required to do so.

While section 172(a)(1)(A) provides a mechanism to classify nonattainment areas, section 172(a)(2)(D) provides that the attainment date extensions described in section 172(a)(2)(A) do not apply to nonattainment areas having specific attainment dates that are addressed under other provisions of the part D of the CAA. Section 192(a), of part D, specifically provides an attainment date for areas designated as nonattainment for the Pb NAAQS. Therefore, EPA has legal authority to classify lead nonattainment areas, but the 5 year attainment date under section 192(a) cannot be extended pursuant to section 172(a)(2)(D). Based on this limitation, EPA proposed not to establish classifications within the 5 year interval for attaining any new or revised NAAQS. This approach is consistent with EPA's previous classification decision for Pb in the 1992 General Preamble (*See* 57 FR 13549, April 16, 1992).

2. Comments and Responses

Several commenters stated that they disagreed with EPA's proposal not to classify lead nonattainment areas under CAA section 172(a)(1)(A). The commenters stated that existing nonattainment areas, meaning areas that have not yet achieved the pre-existing Pb NAAQS, would benefit from more rigorous SIP requirements associated with classifications. The commenters stated that such classifications are appropriate not only for deadline extensions (not applicable in this case, as EPA notes), but ''for other purposes''. The commenters state that such purposes should include lower emissions thresholds for defining major stationary sources, higher offset ratios, and a more ambitious definition of reasonable further progress.

EPA stated in the proposed rule, that while section 172(a)(1)(A) provides a mechanism to classify nonattainment areas, section 172(a)(2)(D) provides that the attainment date extensions described in section 172(a)(2)(A) do not apply to nonattainment areas having specific attainment dates that are addressed under other provisions of part D of the CAA. Based on this limitation, EPA proposed not to establish classifications within the 5 year interval for attaining any new or revised NAAQS. This approach is consistent with EPA's previous classification decision for Pb in the 1992 General Preamble (*See* 57 FR 13549, April 16, 1992) notes that subpart 2 of part D of the CAA specifies mandatory control measures required for areas with different classifications for the ozone standard, including such items as higher offset ratios and specific percentage requirements for reasonable further progress. Areas with higher classifications are subject to more stringent controls, but also receive additional time to attain the standard. Subpart 5 of part D contains no such provisions, but instead requires submittal of a SIP within 18 months of designation of an area as nonattainment, and requires attainment for all areas as expeditiously as practicable, but no later than 5 years following designation. Although EPA does have authority to establish classifications for Pb, EPA continues to believe, taking into consideration these differing statutory schemes (and particularly the requirement to attain as expeditiously as practicable, but no later than 5 years from designation) that it is not appropriate or necessary to establish classifications for the revised Pb NAAQS.

3. Final

The EPA is finalizing the guidance for classifications as provided in the proposed rule. Therefore, there will be no classifications under the revised Pb NAAQS.

D. Section 110(a)(2) Lead NAAQS Infrastructure Requirements

1. Proposal

Under section 110(a)(1) and (2) of the CAA, all states are required to submit plans to provide for the implementation, maintenance, and enforcement of any new or revised NAAQS. Section 110(a)(1) and (2) require states to address basic program elements, including requirements for emissions inventories, monitoring, and modeling, among other things. States are required to submit SIPs to EPA which demonstrate that these basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) listed below, set forth the elements that a state's program must contain in the SIP.[113] The list of section 110(a)(2) NAAQS implementation requirements are the following:

- Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.
- Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation and permitting of new/modified sources.
- Interstate transport: Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or

[113] Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

other type of emissions activity in the state from contributing significantly to nonattainment in another state or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.

• Adequate resources: Section 110(a)(2)(E) requires states to provide assurances of adequate funding, personnel and legal authority for implementation of their SIPs.

• Stationary source monitoring system: Section 110(a)(2)(F) requires states to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.

• Emergency power: Section 110(a)(2)(G) requires states to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.

• Provisions for SIP revision due to NAAQS changes or findings of inadequacies: Section 110(a)(2)(H) requires states to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.

• Section 121 consultation with local and Federal government officials: Section 110(a)(2)(J) requires states to meet applicable local and Federal government consultation requirements of section 121.

• Section 127 public notification of NAAQS exceedances: Section 110(a)(2)(J) requires states to meet applicable requirements of section 127 relating to public notification of violating NAAQS.

• PSD and visibility protection: Section 110(a)(2)(J) also requires states to meet applicable requirements of title I part C related to prevention of significant deterioration and visibility protection.

• Air quality modeling/data: Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.

• Permitting fees: Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.

Consultation/participation by affected local government: Section 110(a)(2)(M) requires states to provide for consultation and participation by local political subdivisions affected by the SIP.

2. Final

The EPA is finalizing the guidance related to the submittal of SIPs to address the infrastructure requirements of section 110(a)(1) and (2) as stated in the proposed rule.

E. Attainment Dates

1. Proposal

As discussed in the proposal, the maximum deadline date by which an area is required to attain the Pb NAAQS is determined by the effective date of the nonattainment designation for the area. For areas designated nonattainment for the revised Pb NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). In the proposed rule, EPA stated it would determine whether an area had demonstrated attainment of the Pb NAAQS by evaluating air quality monitoring data from the one, two, or three previous years as available.

2. Comments and Responses

A commenter stated that the attainment deadline for the current nonattainment and maintenance areas should be three years.

Under the CAA, states are required to attain as expeditiously as practicable (but in no case later than five years). If it is practicable for a nonattainment area to attain the standard within three years, then the SIP must provide for attainment within three years. If, however, attainment within three years is not practicable, then EPA has no authority to require attainment by that deadline.

2. Final

The EPA is generally finalizing the guidance related to attainment dates as provided in the proposed rule. States with nonattainment areas will be required to attain the standard as expeditiously as practicable, but in no event later than five years from the effective date of the nonattainment designation. EPA wishes to clarify that it will be considering air quality monitoring data from the three previous years, as available, in determining whether areas have demonstrated attainment (i.e., EPA would only consider data for less than the three previous years in situations where the data for all three years was unavailable).

F. Attainment Planning Requirements

Any state containing an area designated as nonattainment with respect to the Pb NAAQS must develop for submission, a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable deadline (see sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the lead part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment. Additional specific plan requirements for lead nonattainment areas are outlined in 40 CFR 51.117.

The general part D nonattainment plan requirements are set forth in section 172 of the CAA. Section 172(c) specifies that SIPs submitted to meet the part D requirements must, among other things, include Reasonably Available Control Measures (RACM) (which includes Reasonably Available Control Technology (RACT)), provide for Reasonable Further Progress (RFP), include an emissions inventory, require permits for the construction and operation of major new or modified stationary sources (see also CAA section 173), contain contingency measures, and meet the applicable provisions of section 110(a)(2) of the CAA related to the general implementation of a new or revised NAAQS. It is important to note that lead nonattainment SIPs must meet all of the requirements related to part D of the CAA, including those specified in section 172(c), even if EPA does not provide separate specific guidance for each provision.

1. RACM/RACT for Lead Nonattainment Areas

a. Proposal

Lead nonattainment area SIPs must contain RACM (including RACT) that address sources of ambient lead concentrations. In general, EPA believes that lead NAAQS violation issues will usually be attributed to emissions from stationary sources. In EPA's 2002 National Emissions Inventory (NEI), there were 12 stationary sources in the country with lead emissions over 5 tons per year, and 124 sources over 1 ton of lead emissions per year.

Some emissions that contribute to violations of the Pb NAAQS may also be attributed to smaller area sources. At primary lead smelters, the process of reducing concentrated ore to lead involves a series of steps, some of which are completed outside of buildings, or inside of buildings that are not totally enclosed. Over a period of time, emissions from these sources have been deposited in neighboring communities (e.g., on roadways, parking lots, yards, and off-plant property). This historically deposited lead, when disturbed, may be

re-entrained into the ambient air and may contribute to violations of the Pb NAAQS in affected areas.

The first step in addressing RACM for lead is identifying potential control measures for sources of lead in the nonattainment area. A suggested starting point for specifying RACM in lead nonattainment area SIPs is outlined in appendix 1 of the guidance entitled ''State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'', 58 FR 67752, December 22, 1993. If a state is aware of facts, or receives substantive public comments, that demonstrate through appropriate documentation, that additional control measures may be reasonably available in a specific area, the measures should be added to the list of available measures for consideration in that particular area.

While EPA does not presume that these control measures are reasonably available in all areas, a reasoned justification for rejection of any available control measure should be prepared. If it can be shown that measures, considered both individually as well as in a group, are unreasonable because emissions from the affected sources are insignificant, then the measures may be excluded from further consideration as they would not be representative of RACM for the affected area. The resulting control measures should then be evaluated for reasonableness, considering their technological feasibility and the cost of control in the area for which the SIP applies. In the case of public sector sources and control measures, this evaluation should consider the impact and reasonableness of the measures on the municipal, or other governmental entity that must assume the responsibility for their implementation. It is important to note that a state should consider the feasibility of implementing measures in part when full implementation would be infeasible. A reasoned justification for partial or full rejection of any available control measure, including those considered or presented during the state's public hearing process, should be prepared. The justification should contain a detailed explanation, with appropriate documentation, as to why each rejected control measure is deemed infeasible or otherwise unreasonable for implementation.

Economic feasibility considers the cost of reducing emissions and the difference between the cost of the emissions reduction approach at the particular source in question and the costs of emissions reduction approaches that have been implemented at other similar sources. Absent other indications, EPA as a general matter expects that it is reasonable for similar sources to bear similar costs of emissions reduction. Economic feasibility for RACT purposes is largely determined by evidence that other sources in a particular source category have in fact applied the control technology or process change in question. The EPA also encourages the development of innovative measures not previously employed which may also be technically and economically feasible.

The capital costs, annualized costs, and cost effectiveness of an emissions reduction technology should be considered in determining whether a potential control measure is reasonable for an area or state. One available reference for calculating costs is the EPA Air Pollution Control Cost Manual,[114] which describes the procedures EPA uses for determining these costs for stationary sources. The above costs should be determined for all technologically feasible emission reduction options. States may give substantial weight to cost effectiveness in evaluating the economic feasibility of an emission reduction technology. The cost effectiveness of a technology is its annualized cost ($/year) divided by the emissions reduced (i.e., tons/year) which yields a cost per amount of emission reduction ($/ton). Cost effectiveness provides a value for each emission reduction option that is comparable with other options and other facilities. With respect to a given pollutant, a measure is likely to be reasonable if it has a cost per ton similar to other measures previously employed for that pollutant. In addition, a measure is likely to be reasonable from a cost effectiveness standpoint if it has a cost per ton similar to that of other measures needed to achieve expeditious attainment in the area within the CAA's timeframes.

The fact that a measure has been adopted or is in the process of being adopted by other states is also an indicator (though not a definitive one) that the measure may be technically and economically feasible for another state. We anticipate that states may decide upon RACT and RACM controls that differ from state to state, based on the state's determination of the most effective strategies given the relevant mixture of sources and potential controls in the relevant nonattainment areas, and differences in difficulty of attaining expeditiously. Nevertheless, states should consider and address RACT and RACM measures developed for other areas, as part of a well reasoned RACT and RACM analysis. The EPA's own evaluation of SIPs for compliance with the RACT and RACM requirements will include comparison of measures considered or adopted by other states.

In considering what level of control is reasonable, EPA is not adopting a specific dollar per ton cost threshold for RACT. Areas with more serious air quality problems typically will need to obtain greater levels of emissions reductions from local sources than areas with less serious problems, and it would be expected that their residents could realize greater public health benefits from attaining the standard as expeditiously as practicable. For these reasons, we believe that it will be reasonable and appropriate for areas with more serious air quality problems and higher design values to impose emission reduction requirements with generally higher costs per ton of reduced emissions than the cost of emissions reductions in areas with lower design values. In addition, where essential reductions are more difficult to achieve (e.g., because many sources are already controlled), the cost per ton of control may necessarily be higher.

The EPA believes that in determining appropriate emission control levels, the state should consider the collective public health benefits that can be realized in the area due to projected improvements in air quality. Because EPA believes that RACT requirements will be met where the state demonstrates timely attainment, and areas with more severe air quality problems typically will need to adopt more stringent controls, RACT level controls in such areas will require controls at higher cost effectiveness levels ($/ton) than areas with less severe air quality problems.

In identifying the range of costs per ton that are reasonable, information on benefits per ton of emission reduction can be useful as one factor to consider. It should be noted that such benefits estimates are subject to significant uncertainty and that benefits per ton vary in different areas. Nonetheless this information could be used in a way that recognizes these uncertainties. If a per ton cost of implementing a measure is significantly less than the anticipated benefits per ton, this would be an indicator that the cost per ton is reasonable. If a source contends that a source-specific RACT level should be

[114] *EPA Air Pollution Control Cost Manual—Sixth Edition* (EPA 452/B–02–001), EPA Office of Air Quality Planning and Standards, Research Triangle Park, NC, Jan. 2002.

established because it cannot afford the technology that appears to be RACT for other sources in its source category, then the source should support its claim by providing detailed and verified information regarding the impact of imposing RACT on:

- Fixed and variable production costs ($/unit),
- Product supply and demand elasticity,
- Product prices (cost absorption vs. cost pass-through),
- Expected costs incurred by competitors,
- Company profits, and
- Employment costs.

The technical guidance entitled ''Fugitive Dust Background Document and Technical Information Document for Best Available Control Measures'' (EPA–450/2–92–004, September 1992) provides an example for states on how to analyze control costs for a given area.

Once the process of determining RACM for an area is completed, the individual measures should then be converted into a legally enforceable vehicle (e.g., a regulation or permit program) (see section 172(c)(6) and section 110(a)(2)(A) of the CAA). The regulations or other measures submitted should meet EPA's criteria regarding the enforceability of SIPs and SIP revisions. These criteria were stated in a September 23, 1987 memorandum (with attachments) from J. Craig Potter, Assistant Administrator for Air and Radiation; Thomas L. Adams, Jr., Assistant Administrator for Enforcement and Compliance Monitoring; and S. Blake, General Counsel, Office of the General Counsel; entitled ''Review of State Implementation Plans and Revisions of Enforceability and Legal Sufficiency.'' As stated in this memorandum, SIPs and SIP revisions that fail to satisfy the enforceability criteria should not be forwarded for approval. If they are submitted, they will be disapproved if, in EPA's judgment, they fail to satisfy applicable statutory and regulatory requirements.

The EPA's historic definition of RACT is the lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.[115] RACT applies to the ''existing sources'' of lead in an area including stack emissions, industrial process fugitive emissions, and industrial fugitive dust emissions (e.g., on-site haul roads, unpaved staging areas at the facility, etc.) (see section 172(c)(1)). The EPA's previous guidance for implementing the pre-existing Pb NAAQS recommends that stationary sources which emit a total of 5 tpy of lead or lead compounds, measured as elemental lead, be the minimum starting point for RACT analysis (see 58 FR 67750, December 22, 1993). Further, EPA's existing guidance recommends that available control technology be applied to those existing sources in the nonattainment area that are reasonable to control in light of the attainment needs of the area and the feasibility of such controls. Thus, under existing guidance, a state's control technology analysis may need to include sources which actually emit less than 5 tpy of lead or lead compounds in the area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of control for the area.

Given the proposal to promulgate a revised Pb NAAQS that is significantly lower than the current level of 1.5 μg/m^3, EPA requested comment on the appropriate threshold for the minimum starting point for future Pb RACT analyses for stationary lead sources in nonattainment areas. In the proposed rule, EPA requested comment on the emissions level associated with the minimum network source monitoring requirements. These source levels range from 200 kg/yr to 600 kg/yr. The EPA also stated that one possible approach for RACT is to recommend that RACT analyses for Pb sources be consistent with sources that are required to monitor such that all stationary sources above 200 kg/yr to 600 kg/yr should undergo a RACT review. EPA also requested comment on source monitoring for stationary sources that emit lead emissions in amounts that have potential to cause ambient levels at least one-half the selected NAAQS level. This suggests another potential recommendation for the starting point for the RACT analysis. The EPA sought comment on these ideas as well as any information which commenters could provide that would help inform EPA's recommendation on an appropriate emissions threshold for initiating RACT analyses.

b. Comments and Responses

Several commenters stated that given the proposed level of the lead NAAQS that EPA should set the threshold for RACT analysis for stationary sources at a threshold level similar to the level being considered for the source monitoring requirements, which is between 200 kg/yr–600 kg/yr. Several commenters suggested a lower threshold (such as 45 kg/year) or stated that depending on the attainment needs for the affected area, it may be necessary to evaluate control technology that is reasonably available for sources with actual emissions that are lower than the recommended RACM/RACT threshold to take into consideration the actual attainment needs for the affected area. One commenter suggested the threshold should be set only at a level at which an exceedance of the NAAQS is expected, while another suggested it should be set no higher than that level.

The EPA believes that it is appropriate to set the recommended threshold for the RACT analysis for the new standard at 0.5 tpy. The existing Pb NAAQS is set at 1.5 μg/m^3 and the existing threshold for RACT analysis is 5 tpy. Since the standard is being reduced by a factor of ten, from 1.5 μg/m^3 to 0.15 μg/m^3, it is appropriate to also reduce the threshold for RACT analysis by a factor of 10, from 5 tpy to 0.5 tpy. Furthermore, the monitor siting criteria include a requirement for monitoring agencies to conduct monitoring taking into account sources that are expected to exceed the NAAQS, and require monitoring for sources which emit Pb at a rate of one ton per year. Although EPA expects that sources emitting less than one tpy may also contribute to violations of the revised Pb NAAQS, EPA believes that the one tpy requirement in the monitor siting criteria provides a benchmark that is more likely to clearly identify sources that would contribute to exceedances of the NAAQS. Accordingly, using 50% of that figure (0.5 tpy) as the threshold for RACT analysis is generally consistent with EPA's consideration in the proposal of setting the RACT threshold to include those stationary sources that emit lead emissions in amounts that have the potential to cause ambient levels at least one-half the selected NAAQS.

EPA believes that setting the RACT threshold higher (e.g., at 1 tpy) would not be appropriate because it is likely that in a nonattainment area sources emitting less than one tpy are contributing to the nonattainment of the NAAQS. EPA also does not believe a lower threshold is warranted as a general matter, but EPA agrees with commenters that the state's control technology analysis should also include, as appropriate, sources which actually emit less than the threshold level of 0.5 tpy of lead or lead compounds in the

[115] *See* for example, 44 FR 53762 (September 17, 1979) and footnote 3 of that notice. Note that EPA's emissions trading policy statement has clarified that the RACT requirement may be satisfied by achieving ''RACT equivalent'' emission reductions in the aggregate from the full set of existing stationary sources in the area. *See* also EPA's economic incentive proposal which reflects the Agency's policy guidance with respect to emissions trading, 58 FR 11110, February 23, 1993.

area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of controls for the affected area.

Several commenters stated that in the proposed rule EPA suggests that the 1993 guidance document, which lists control measures as a starting point for states' consideration, puts the burden on the public to demonstrate through appropriate documentation that additional control measures may be reasonably available in a particular circumstance for an area. The commenters further stated that in light of an anticipated substantial reduction in the Pb NAAQS, as well as the failure of the remaining two existing nonattainment areas to achieve attainment of the pre-existing (1978) NAAQS under the 1993 guidance, that both EPA and the states should bear the principal responsibility for developing an updated roster of successful control measures.

As stated in the proposed rule, EPA believes that the regulations, policies, and guidance currently in place for the implementation of the pre-existing Pb NAAQS are still appropriate to address the issues required to implement the revised Pb NAAQS. The EPA believes that these guidance, policies, and regulations should be used by states, local, and Tribal governments as a starting point to begin implementation of the revised Pb NAAQS. The EPA expects that as states gain additional experience with implementing the revised NAAQS, additional information on successful control measures will become available to states, EPA, and the public. The EPA will, as appropriate, review, and revise or update policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

c. Final

The EPA is finalizing the guidance related to RACM (including RACT) for lead nonattainment areas consistent with the proposed rule. Based upon the above considerations regarding the scale of the reduction in the standard, the final monitor siting criteria, and the public comments received related to the starting point for a RACT analysis, EPA is recommending a threshold for RACT analysis such that at least all stationary sources emitting 0.5 tpy or more should undergo a RACT review.

2. Demonstration of Attainment for Lead Nonattainment Areas

a. Proposal

The SIPs for lead nonattainment areas should provide for the implementation of control measures for point and area sources of lead emissions which demonstrate attainment of the Pb NAAQS as expeditiously as practicable, but no later than the applicable statutory attainment date for the area (*see* also 40 CFR 51.117(a) for additional control strategy requirements). Therefore, if a state adopts less than all available measures in an area but demonstrates, adequately, that reasonable further progress (RFP), and attainment of the Pb NAAQS are assured, and the application of all such available measures would not result in attainment any faster, then a plan which requires implementation of less than all technologically and economically available measures may be approved (*see* 44 FR 20375 (April 4, 1979) and 56 FR 5460 (February 11, 1991)). The EPA believes that it would be unreasonable to require that a plan which demonstrates attainment include all technologically and economically available control measures even though such measures would not expedite attainment. Thus, for some sources in areas which demonstrate attainment, it is possible that some available control measures may not be ''reasonably'' available because their implementation would not expedite attainment for the affected area.

b. Final

The EPA is finalizing the guidance related to demonstration of attainment for lead nonattainment areas as stated in the proposed rule. Further discussion of modeling for attainment and other topics is presented below.

3. Reasonable Further Progress (RFP)

a. Proposal

Part D SIPs must provide for RFP (see section 172(c)(2) of the CAA). Section 171 of the CAA defines RFP as ''such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date.'' Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions generally sufficient to maintain linear progress toward attainment by the applicable attainment date. The EPA believes that RFP for lead nonattainment areas should be met by ''adherence to an ambitious compliance schedule'' which is expected to periodically yield significant emission reductions, and as appropriate, linear progress.[116] The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) in the affected areas and accurately indicate the corresponding annual emission reductions to be achieved. In reviewing the SIP, EPA believes that it is appropriate to expect early implementation of less technology-intensive control measures (e.g., controlling fugitive dust emissions at the stationary source, as well as required controls on area sources) while phasing in the more technology-intensive control measures, such as those involving the installation of new hardware. Finally, failure to implement the SIP provisions required to meet annual incremental reductions in emissions (i.e., RFP) in a particular area could result in the application of sanctions as described in section 179(b) of the CAA (pursuant to a finding under section 179(a)(4)), and the implementation of contingency measures required by section 172(c)(9) of the CAA.

b. Comments and Responses

Several commenters stated that EPA's proposal related to RFP would allow states to avoid the need to demonstrate linear progress towards attainment, departing from the typical method used, and statutorily required in some cases, for other criteria pollutants. These commenters further state that the recognition that some nonattainment urban areas have numerous sources contributing to excessive ambient levels of lead which undermines the reasoning employed to justify a non-linear approach in the context of single source nonattainment areas. If areas with large sources install key controls early on in the attainment process, and thus achieve attainment ahead of schedule, that would advance the goals and requirements of the CAA.

Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions generally sufficient to maintain linear progress toward attainment by the applicable attainment date. As EPA has previously noted, we expect that some nonattainment designations will be attributable to a single stationary source, and others may be attributable to a number of smaller sources. Where a single source is the cause of

[116] As previously stated in the proposed rule, EPA believes that most lead nonattainment problems will most likely be due to emissions from stationary sources of lead. For this reason EPA believes that the RFP for Pb should parallel the RFP policy for SO2 (*see* General Preamble, 57 FR 13545, April 16, 1992).

nonattainment, EPA would not expect linear progress towards attainment. Rather, there may be relatively less progress while the source adopts non-technological control measures and begins to install necessary technological controls, and then significant progress towards attainment in a short period of time once all the controls are operational. EPA expects that, since states are required to attain the standard as expeditiously as practicable, the SIP will require large sources to install ''key controls'' as expeditiously as practicable. At the same time, where a number of sources are contributing to nonattainment, it is more reasonable to expect that controls (both technological and non-technological) may be adopted at different times, making linear progress a more reasonable expectation. To accommodate both of these possible situations, EPA concludes it is appropriate that RFP for lead nonattainment areas should be met by the strict adherence to an ambitious compliance schedule which is expected to periodically yield significant emission reductions, and, to the extent appropriate, linear progress.

c. Final

The EPA is finalizing the guidance related to reasonable further progress (RFP) consistent with the proposed rule. The EPA believes that RFP for lead nonattainment areas should be met by the strict adherence to an ambitious compliance schedule which is expected to periodically yield significant emission reductions, and to the extent appropriate, linear progress. The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) and accurately indicate the corresponding annual emission reductions to be achieved. In reviewing the SIP, EPA believes that it is appropriate to expect early implementation of less technology-intensive control measures (e.g., work practices to control fugitive dust emissions at the stationary sources) while phasing in the more technology-intensive control measures, such as those involving the installation of new hardware. The EPA believes that the expeditious implementation of RACM/RACT at affected sources within the nonattainment area is an appropriate approach to assure attainment of the Pb NAAQS in an expeditious manner.

4. Contingency Measures

a. Proposal

Section 172(c)(9) of the CAA defines contingency measures as measures in a SIP that are to be implemented if an area fails to achieve and maintain RFP, or fails to attain the NAAQS by the applicable attainment date. Contingency measures must be designed to become effective without further action by the state or the Administrator, upon determination by EPA that the area has failed to achieve, or maintain reasonable further progress (RFP), or attain the Pb NAAQS by the applicable statutory attainment date. Contingency measures should consist of available control measures that are not already included in the primary control strategy for the affected area.

Contingency measures are important for lead nonattainment areas, which may violate the NAAQS generally due to emissions from stationary sources, for several reasons. First, process and fugitive emissions from these stationary sources, and the possible re-entrainment of historically deposited emissions, have historically been difficult to quantify. Therefore, the analytical tools for determining the relationship between reductions in emissions, and resulting air quality improvements, can be subject to some uncertainties. Second, emission estimates and attainment analysis can be influenced by overly optimistic assumptions about fugitive emission control efficiency.

Examples of contingency measures for controlling area source fugitive emissions may include measures such as stabilizing additional storage piles. Examples of contingency measures for process-related fugitive emissions include increasing the enclosure of buildings, increasing air flow in hoods, modifying operation and maintenance procedures, etc. Examples of contingency measures for stack sources include reducing hours of operation, changing the feed material to lower lead content, and reducing the occurrence of malfunctions by modifying operation and maintenance procedures, etc.

Section 172(c)(9) provides that contingency measures should be included in the state SIP for a lead nonattainment area and shall ''take effect without further action by the state or the Administrator.'' The EPA interprets this requirement to mean that no further rulemaking actions by the state, or EPA, would be needed to implement the contingency measures (*see* generally 57 FR 12512 and 13543–13544). The EPA recognizes that certain actions, such as the notification of sources, modification of permits, etc., may be needed before a measure could be implemented. However, states must show that their contingency measures can be implemented with only minimal further action on their part and with no additional rulemaking actions such as public hearings or legislative review. After EPA determines that a lead nonattainment area has failed to maintain RFP or timely attain the Pb NAAQS, EPA generally expects all actions needed to affect full implementation of the measures to occur within 60 days after EPA notifies the state of such failure. The state should ensure that the measures are fully implemented as expeditiously as practicable after the requirement takes effect.

b. Comments and Responses

Several commenters stated that EPA noted in the proposed rulemaking that ''contingency measures are important for lead nonattainment areas'' and that the CAA requires that contingency measures must ''take effect without further action'' by the state or the Administrator.'' However, the commenters stated that EPA then interprets the ''take effect without further action'' requirement too broadly, indicating that it is satisfied if the contingency measure can take effect without further rulemaking. The EPA would allow contingency measures that require a state to undertake a permit modification before the contingency measures would go into effect.

As stated in the proposed rule, section 172(c)(9) of the CAA defines contingency measures as measures in a SIP that are to be implemented if an area fails to achieve and maintain RFP, or fails to attain the NAAQS by the applicable attainment date. Contingency measures must be designed to become effective without further action by the state or the Administrator, upon determination by EPA that the area has failed to achieve, or maintain reasonable further progress, or attain the Pb NAAQS by the applicable statutory attainment date. As stated in the proposed rule, the EPA believes that this requirement means that no further rulemaking actions by the state, or EPA, would be needed to implement the contingency measures (*see* generally 57 FR 12512 and 13543–13544). The EPA recognizes that in some circumstances minimal actions, such as the notification of sources, modification of permits, etc., may be needed before a measure could be implemented. However, as also stated in the proposed rule, states must show that their contingency measures can be implemented with only minimal further action on their part and that no additional rulemaking actions will be required, such as public hearings or legislative review, which will delay the expeditious implementation of the

contingency measures in the affected area. To the extent that modifications in title V operating permits would be required to implement contingency measures, the SIP should provide that those permits will be issued or modified prior to the time such contingency measures may be needed to include alternative operating scenarios providing for implementation of the contingency measures if necessary. *See* 40 CFR 70.6(a)(9). The EPA generally expects that all actions, including those actions related to modification of permits, that are needed to affect full implementation of the contingency measures, must occur within 60 days following EPA's notification to the state of such failure.

c. Final

The EPA is finalizing the guidance related to contingency measures for lead nonattainment areas as stated in the proposed rule. The key requirements associated with contingency measures are: (1) Contingency measures must be fully adopted rules or control measures that are ready to be implemented as expeditiously as practicable upon a determination by EPA that the area has failed to achieve, or maintain reasonable further progress, or attain the Pb NAAQS by the applicable statutory attainment date; (2) The SIP should contain trigger mechanisms for the contingency measures and specify a schedule for implementation; and (3) The SIP must indicate that the measures will be implemented without further action (or only minimal action) by the state or by the Administrator. The contingency measures should also consist of control measures for the area that are not already included in the control strategy for the attainment demonstration of the SIP. The EPA believes that the measures should provide for emission reductions that are at least equivalent to one year's worth of reductions needed for the area to meet the requirements of RFP, based on linear progress towards achieving the overall level of reductions needed to demonstrate attainment.

5. Nonattainment New Source Review (NSR) and Prevention of Significant Deterioration (PSD) Requirements

a. Proposal

The PSD and nonattainment NSR programs contained in parts C and D of Title I of the CAA govern preconstruction review and permitting programs for any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator. The EPA rules addressing these regulations can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S.

States containing areas designated as nonattainment for the Pb NAAQS must submit SIPs that address the requirements of nonattainment NSR. Specifically, section 172(c)(5) of the CAA requires that states which have areas designated as nonattainment for the Pb NAAQS must submit, as a part of the nonattainment area SIP, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area, in accordance with the permit requirements pursuant to section 173 of the CAA. Likewise, areas designated attainment must submit infrastructure SIPs that address the requirements of PSD pursuant to section 110(a)(2)(C).

Stationary sources that emit lead are currently subject to regulation under existing requirements for the preconstruction review and approval of new and modified stationary sources. The existing requirements, referred to collectively as the New Source Review (NSR) program, require all major and certain minor stationary sources of any air pollutant for which there is a NAAQS to undergo review and approval prior to the commencement of construction.[117] The NSR program is composed of three different permit programs:

- Prevention of Significant Deterioration (PSD).
- Nonattainment NSR (NA NSR).
- Minor NSR.

The PSD program and nonattainment NSR programs, contained in parts C and D, respectively, of Title I of the CAA, are often referred to as the major NSR program because these programs regulate only major sources.

The PSD program applies when a major source, that is located in an area that is designated as attainment or unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.[118] The nonattainment NSR program applies when a major source of a criteria pollutant that is located in an area that is designated as nonattainment for that pollutant is constructed or undergoes a major modification. The minor NSR program addresses both major and minor sources that undergoes construction or modification activities that do not qualify as major, and it applies regardless of the designation of the area in which a source is located.

The national regulations that apply to each of these programs are located in the CFR as shown below:

	Applications
PSD	40 CFR 52.21, 40 CFR 51.166, 40 CFR 51.165(b).
NA NSR	40 CFR 52.24, 40 CFR 51.165, 40 CFR part 51, Appendix S.
Minor NSR	40 CFR 51.160–164.

The PSD requirements include but are not limited to the following:

- Installation of Best Available Control Technology (BACT);
- Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
- Notification of Federal Land Manager of nearby Class I areas; and
- Public comment on permit.

Nonattainment NSR requirements include but are not limited to:

- Installation of Lowest Achievable Emissions Rate (LAER) control technology;
- Offsetting new emissions with creditable emissions reductions;
- A certification that all major sources owned and operated in the state by the same owner are in compliance with all applicable requirements under the CAA;
- An alternative siting analysis demonstrating that the benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
- Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires ''* * * regulation of the modification and construction of any stationary source * * * as necessary to assure that the [NAAQS] are achieved.''

Areas which are newly designated as nonattainment for the Pb NAAQS as a result of any changes made to the NAAQS will be required to adopt a nonattainment NSR program to address major sources of lead where the program does not currently exist for the Pb NAAQS. Prior to adoption of the SIP

[117] The terms ''major'' and ''minor'' define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not ''major.'' ''Major'' is defined by the applicable regulations—PSD or nonattainment NSR.

[118] In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

revision addressing NSR for lead nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply.

b. Comments and Responses

Several commenters stated that given the significant changes being proposed for the revised Pb NAAQS, EPA must promptly undertake rulemaking action in order to satisfy the PSD requirements related to the revised Pb NAAQS. The commenters further stated that EPA should revise the current regulations related to the establishment of maximum allowable increases or increments for lead under 40 CFR 51.166(a), and a substantial reduction in the significant/de minimis emissions levels for lead set forth in 40 CFR 51.166(b)(23)(i) and 40 CFR 52.21(b)(23)(i).

As stated previously, the EPA believes that generally, there is sufficient guidance and regulations already in place to fully implement the revised Pb NAAQS. The EPA notes that, under section 110(a)(2)(D), every minor source NSR program must be sufficiently complete and stringent ''to assure that the [NAAQS] are achieved.'' The EPA will as appropriate review and revise and update policies, guidance, and regulations for implementing the revised Pb NAAQS following the promulgation of the NAAQS.

c. Final

The EPA is finalizing the guidance related to nonattainment NSR and PSD requirements for lead nonattainment areas as provided in the proposed rule.

6. Emissions Inventories

a. Proposal

States must develop and periodically update a comprehensive, accurate, current inventory of actual emissions affecting ambient lead concentrations. The emissions inventory is used by states and EPA to determine the nature and extent of the specific control strategy necessary to help bring an area into attainment of the NAAQS. Emissions inventories should be based on measured emissions or documented emissions factors. Generally, the more comprehensive and accurate the inventory, the more effective the evaluation of possible control measures can be for the affected area (see section 172(c)(3) of the CAA).

Pursuant to its authority under section 110 of Title I of the CAA, EPA has long required states to submit emission inventories containing information regarding the emissions of criteria pollutants as well as their precursors. The EPA codified these requirements in 40 CFR part 51, subpart Q in 1979 and amended them in 1987. The 1990 Clean Air Act Amendments (CAAA) revised many of the provisions of the CAA related to attainment of the NAAQS. These revisions established new emission inventory requirements applicable to certain areas that were designated as nonattainment for certain pollutants.

In June 2002, EPA promulgated the Consolidated Emissions Reporting Rule (CERR) (67 FR 39602, June 10, 2002). The CERR consolidates the various emissions reporting requirements that already exist into one place in the Code of Federal Regulations (CFR), and establishes new requirements for the statewide reporting of area (non-point) source and mobile source emissions. The CERR establishes two types of required emissions inventories: (1) Annual inventories, and (2) 3-year cycle inventories. The annual inventory requirement is limited to reporting statewide emissions data from the larger point sources. For the 3-year cycle inventory, states will need to report data from all of their point sources plus all of the area (non-point) and mobile sources on a statewide basis.

By merging emissions information from relevant point sources, area sources, and mobile sources into a comprehensive emission inventory, the CERR allows State, local and tribal agencies to do the following:

- Set a baseline for SIP development.
- Measure their progress in reducing emissions.
- Answer the public's request for information.

The EPA uses the data submitted by the states to develop the National Emission Inventory (NEI). The NEI is used by EPA to show national emission trends, as modeling input for analysis of potential regulations, and other purposes.

Most importantly, states need these inventories to help in the development of control strategies and demonstrations to attain the Pb NAAQS. While the CERR sets forth requirements for data elements, EPA guidance complements these requirements and indicates how the data should be prepared for SIP submissions. Our current regulations at 40 CFR 51.117(e) require states to include in the SIP inventory all point sources that emit 5 or more tons of lead emissions per year. As stated previously, in the proposed rulemaking EPA took comment on whether the recommended threshold for RACT analysis should be less than the current 5 tons/yr (see section VI.F.1), and proposed that if EPA lowered the recommended threshold for RACT in the final rulemaking, we would also revise, to be consistent, the emissions threshold for including sources in the inventory pursuant to 40 CFR 51.117(e). In the proposed rule, we solicited comment on the appropriate threshold for Pb point source inventory reporting requirements.

The SIP inventory must be approved by EPA as a SIP element and is subject to public hearing requirements, whereas the CERR inventory is not. Because of the regulatory significance of the SIP inventory, EPA will need more documentation on how the SIP inventory was developed by the state as opposed to the documentation required for the CERR inventory. In addition, the geographic area encompassed by some aspects of the SIP submission inventory will be different from the statewide area covered by the CERR emissions inventory.

The EPA has proposed the Air Emissions Reporting Rule (AERR) at 71 FR 69 (Jan. 3, 2006). When finalized, the AERR will update, consolidate, and harmonize new emissions reporting requirements with preexisting sets of reporting requirements under the CERR and the NO_X SIP Call. The AERR is expected to be a means by which the Agency will implement additional data reporting requirements for the Pb NAAQS SIP emission inventories.

b. Comments and Responses

One commenter stated that states currently work with regional offices in developing nonattainment area inventories and that this approach should be encouraged. The commenter further indicated that states should be allowed to start with the National Emissions Inventory (NEI) and customize their nonattainment area inventories to analyze nonattainment problems.

The EPA encourages the states to continue to work closely with the EPA Regional Offices in developing their nonattainment area emissions inventories as well as any enhancements that need to be made to the NEI. The EPA encourages the use of the NEI as a tool to assist states in developing their nonattainment area SIP emissions inventory. States, however, are reminded that the nonattainment area SIP emissions inventory is required pursuant to 40 CFR 51.117(e) and must be approved by EPA pursuant to the CAA, and is subject to the public hearing requirements pursuant to section 110(a)(2).

One commenter stated that EPA should develop additional guidance on emission inventories related to the nonattainment area SIP submittal

because the requirements under the CERR and the AERR may not be enough to adequately address the emissions inventory requirements related to the attainment demonstration for the SIP.

The EPA will review the need for additional guidance concerning the emissions inventories related to the nonattainment area SIP submittal on an ongoing basis. As stated previously, EPA believes that the current guidance, policies, and regulations provide a sufficient basis for states to implement the revised Pb NAAQS at this time. The EPA, as appropriate, will review and revise or update these policies, guidance, and regulations to provide for effective implementation of the Pb NAAQS.

Several commenters stated that EPA should revise 40 CFR 51.117(e)(1), relating to the emissions reporting threshold level for lead nonattainment area SIPs. The current threshold level as stated in 51.117(e)(1), requires that the point source inventory on which the summary of the baseline lead emissions inventory is based must contain all sources that emit 5 or more tpy of lead.

The EPA agrees with the commenters that the requirement for the emissions inventory reporting threshold for lead nonattainment SIPs, as stated in 40 CFR 51.117(e)(1), should be revised to reflect the stringency of the revised Pb NAAQS. In the proposed rule, EPA proposed to revise the current threshold level for emissions inventory reporting from 5 tpy to be consistent with the threshold for the analysis of RACM/RACT control measures. As discussed above, EPA is setting the threshold for RACT analysis at 0.5 tpy. EPA concludes it is also appropriate to set the threshold level of the emissions inventory reporting requirement at 0.5 tpy.

c. Final

The EPA is finalizing the guidance contained related to the emissions inventories requirements for the Pb NAAQS as provided in the proposed rule. The EPA is updating the emissions reporting requirements for lead nonattainment area SIPs stated in 40 CFR 51.117(e)(1) by revising the source emission inventory reporting threshold from 5 tpy to 0.5 tpy.

7. Modeling

a. Proposal

The lead SIP regulations found at 40 CFR 51.117 require states to employ atmospheric dispersion modeling for the demonstration of attainment for areas in the vicinity of point sources listed in 40 CFR 51.117(a)(1). To complete the necessary dispersion modeling, meteorological, and other data are necessary. Dispersion modeling should follow the procedures outlined in EPA's latest guidance document entitled ''Guideline on Air Quality Models''. This guideline indicates the types and historical records for data necessary for modeling demonstrations (e.g., on-site meteorological stations, 12 months of meteorological data are required in order to demonstrate attainment for the affected area).

b. Comments and Responses

One commenter stated that the SIPs for lead nonattainment areas should provide for the implementation of control measures for point and area sources of lead emissions which demonstrate attainment of the lead NAAQS as expeditiously as practicable, but no later than the applicable statutory attainment date for the area. The commenter further stated that they believe that the requirements currently stated under 40 CFR 51.117(a)(1), related to additional control strategy requirements, should be revised to reflect the stringency of the revised lead NAAQS. The commenter stated that specifically, the threshold level of 25 tpy as stated in 40 CFR 51.117(a)(1), related to modeling for point source emissions, should be revised to reflect the stringency of the revised NAAQS.

The EPA agrees with the commenter that lead nonattainment area SIPs must provide for the implementation of control measures for point and area source emissions of lead in order to demonstrate attainment of the Pb NAAQS as expeditiously as practicable, but no later than the attainment date for the affected area. EPA notes that 40 CFR 51.117(a) provides that states must include, as a part of their attainment modeling demonstration, an analysis showing that the SIP will attain and maintain the standard in areas in the vicinity of certain point sources that are emitting at the level of 25 tpy, and also in ''any other area that has lead air concentrations in excess of the national ambient air quality standard concentration.'' EPA does not believe it is necessary to amend the 25 tpy threshold in 40 CFR 51.117(a)(1) because the provisions of 40 CFR 51.117(a)(2) are sufficient to ensure an adequate attainment demonstration. Accordingly, EPA believes that the current requirements concerning control strategy demonstration as stated in 40 CFR 51.117(a) are adequate for states to develop SIPs which address attainment of the revised Pb NAAQS. In doing the analysis, required under 40 CFR 51.117(a)(2), EPA expects the state will take into consideration all sources of lead emissions within the nonattainment area that may be required to be controlled, taking into consideration the attainment needs of the area.

c. Final

The EPA is finalizing the guidance related to modeling attainment demonstrations for lead nonattainment area SIPs as proposed. The EPA will continue to review whether any additional changes related to modeling demonstrations or applicable modeling guidance are appropriate.

G. General Conformity

1. Proposal

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 *et seq.*), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. Section 176(c) of the CAA requires EPA to promulgate criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. For the purpose of summarizing the general conformity rule, it can be viewed as containing three major parts: Applicability, procedure, and analysis. These are briefly described below.

The general conformity rule covers direct and indirect emissions of criteria pollutants, or their precursors, that are caused by a Federal action, are reasonably foreseeable, and can practicably be controlled by the Federal agency through its continuing program responsibility. The general conformity rule generally applies to Federal actions except: (1) Actions covered by the transportation conformity rule; (2) Actions with respect to associated emissions below specified de minimis levels; and (3) Certain other actions that are exempt or presumed to conform.

The general conformity rule also establishes procedural requirements. Federal agencies must make their conformity determinations available for public review. Notice of draft and final general conformity determinations must be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. Each Federal agency must determine

that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment and maintenance areas with respect to the criteria pollutants under the CAA:[119] Carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter ($PM_{2.5}$ and PM_{10}), and sulfur dioxide (SO_2). The general conformity rule establishes procedural requirements for Federal agencies for actions related to all NAAQS pollutants, both nonattainment and maintenance areas and will apply one year following the promulgation of designations for any new or revised Pb NAAQS.[120]

2. Final

The EPA is finalizing the guidance related to general conformity as provided in the proposed rule.

H. Transition From the Current NAAQS to a Revised NAAQS for Lead

1. Proposal

As discussed in the proposal, EPA believes that Congress's intent, as evidenced by section 110(l), 193, and section 172(e) of the CAA, was to ensure that continuous progress, in terms of public health protection, takes place in transitioning from a current NAAQS for a pollutant to a new or revised NAAQS. Therefore, EPA proposed that the existing NAAQS be revoked one year following the promulgation of designations for any new NAAQS, except that the existing NAAQS will not be revoked for any current nonattainment area until the affected area submits, and EPA approves, an attainment demonstration which addresses the attainment of the new Pb NAAQS.

The CAA contains a number of provisions that indicate Congress's intent to not allow states to alter or remove provisions from implementation plans if the plan revision would jeopardize the air quality protection being provided by the plan. For example, section 110(l) provides that EPA may not approve a SIP revision if it interferes with any applicable requirement concerning attainment and RFP, or any other applicable requirement under the CAA. In addition section 193 of the CAA prohibits the modification of a control, or a control requirement, in effect or required to be adopted as of November 15, 1990 (i.e., prior to the promulgation of the Clean Air Act Amendments (CAAA) of 1990), unless such a modification would ensure equivalent or greater emissions reductions. One other provision of the CAA provides additional insight into Congress's intent related to the need to continue progress towards meeting air quality standards during periods of transition from one standard to another. Section 172(e) of the CAA, related to future modifications of a standard, applies when EPA promulgates a new or revised NAAQS and makes it less stringent than the previous NAAQS. This provision of the CAA specifies that in such circumstances, states may not relax control obligations that apply in nonattainment area SIPs, or avoid adopting those controls that have not yet been adopted as required.

The EPA believes that Congress generally did not intend to permit states to relax levels of pollution control when EPA revises a standard until the new or revised standard is implemented. Therefore, we believe that controls that are required under the current Pb NAAQS, or that are currently in place under the current Pb NAAQS, should generally remain in place until new designations are established and, for current nonattainment areas, new attainment SIPs are approved for any new or revised standard. As a result, EPA proposed that the current Pb NAAQS should stay in place for one year following the effective date of designations for any new or revised NAAQS before being revoked, except in current nonattainment areas, where the existing NAAQS will not be revoked until the affected area submits, and EPA approves, an attainment demonstration for the revised Pb NAAQS. Accordingly, the CAA mechanisms, including sanctions, that help ensure continued progress toward timely attainment would remain in effect for the existing Pb NAAQS, and would apply to existing Pb nonattainment areas.

Pursuant to CAA section 110(l), any proposed SIP revision being considered by EPA after the effective date of the revised Pb NAAQS would be evaluated for its potential to interfere with attainment or maintenance of the new standard. The EPA believes that any area attaining the revised Pb NAAQS would also attain the existing Pb NAAQS, and thus reviewing proposed SIP revisions for interference with the new standard will be sufficient to prevent backsliding. Consequently, in light of the nature of the proposed revision of the Pb NAAQS, the lack of classifications (and mandatory controls associated with such classifications pursuant to the CAA), and the small number of nonattainment areas, EPA believes that retaining the current standard for a limited period of time until SIPs are approved for the new standard in current nonattainment areas, or one year after designations in other areas, will adequately serve the anti-backsliding goals of the CAA.[121]

2. Final

The EPA is finalizing the guidance related to transition from the current NAAQS to the new Pb NAAQS generally consistent with the proposal that the existing standard be retained until one year following the effective date of designations, except that for current nonattainment areas the standard would remain in effect until approval of a SIP for the new standard. EPA notes that the most recent three years of available monitoring data from the East Helena nonattainment area showed no violations of the current standard, although the monitors were shut down in December, 2001 following the shutdown of the large stationary source of lead emissions there. Accordingly, it is unclear whether East Helena will be designated nonattainment for the new standard, or whether it could possibly receive another designation. In the event East Helena is designated unclassifiable or attainment for the new standard, EPA believes it is still appropriate to retain the existing standard until the state submits, and EPA approves, a maintenance SIP for the new standard. Accordingly EPA has amended the proposed text of 40 CFR 50.12 to reflect the possibility that in this specific set of circumstances, the old standard could be revoked upon EPA's approval of a maintenance SIP for the new standard.

VII. Exceptional Events Information Submission Schedule for Lead NAAQS

EPA proposed changes to the original dates for submitting and documenting exceptional event data claims and the Agency is adopting the proposed changes with some minor revisions and they are described below.

Section A presents the information stated in the proposal. Section B

[119] Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

[120] Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c) to ensure that federally supported highway and transit project activities are consistent with (''conform to'') the purpose of the SIP. Transportation conformity applies to areas that are designated nonattainment, and those areas redesignated to attainment after 1990 (''maintenance areas'' with plans developed under CAA section 175A) for transportation-related criteria pollutants. In light of the elimination of Pb additives from gasoline, transportation conformity does not apply to the Pb NAAQS.

[121] The areas that are currently nonattainment for the pre-existing Pb NAAQS are East Helena, Montana and Jefferson County (part)/Herculaneum, Missouri. (*See http://www.epa.gov/oar/oaqps/greenbk/lnc.html)*

summarizes and responds to all comments received regarding exceptional events data submission. Section C provides the final preamble text considering comments received and incorporating final revisions to the proposal.

A. Proposal

The EPA proposed Pb-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe has been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines in 40 CFR 50.14 are generic, and are not always appropriate for Pb given the anticipated schedule for the designations of areas under the proposed Pb NAAQS.

For the specific case of Pb, EPA anticipates that designations under the revised NAAQS may be made in September 2011 based on 2008–2010 data, (or possibly in September 2010 based on 2007–2009 data if sufficient data are available), and thus will depend in part on air quality data collected as late as December 2010 (or December 2009). (Section IV.C of the proposed preamble had a more detailed discussion of the designation schedule and what data EPA intends to use.) There is no way for a State to flag and submit documentation regarding events that happen in October, November, and December 2010 (or 2009) by one year before designation decisions that are made in September 2011 (or 2010).

The proposed revisions to 40 CFR 50.14 involved only changes in submission dates for information regarding claimed exceptional events affecting Pb data. The proposed rule text showed only the changes that would apply if designations are made three years after promulgation; where a deadline would be different if designations were made at the two-year point, the difference in deadline was noted in the proposed preamble. We proposed to extend the generic deadline for flagging data (and providing a brief initial description of the event) of July 1 of the year following the data collection, to July 1, 2009 for data collected in 2006–2007. The proposed extension included 2006 and 2007 data because Governors' designation recommendations will consider 2006–2008 data, and possibly EPA will consider 2006–2008 or 2007–2009 data if complete data for 2008–2010 are not available at the time of final designations. EPA noted that it does not intend to use data prior to 2006 in making Pb designation decisions. The generic event flagging deadline in the Exceptional Events Rule would continue to apply to 2008 and later years following the promulgation of the revised Pb NAAQS. The Governor of a State would be required to submit designation recommendations to EPA a year after promulgation of the revised NAAQS (i.e., in Fall 2009). States would therefore have enough time to flag data and submit their demonstrations and know what 2008 data need to be excluded due to exceptional events when formulating their recommendations to EPA.

For data collected in 2010 (or 2009), we proposed to move up the generic deadline of July 1 for data flagging to May 1, 2011 (or May 1, 2010) (which is also the applicable deadline for certifying data in AQS as being complete and accurate to the best knowledge of the responsible monitoring agency head). This would give a State less time, but EPA believes still sufficient time, to decide what 2010 (or 2009) data to flag, and would allow EPA to have access to the flags in time for EPA to develop its own proposed and final plans for designations.

Finally, EPA proposed to make the deadline for submission of detailed justifications for exclusion of data collected in 2006 through 2008 be September 15, 2010 for the three year designation schedule, or September 15, 2009 under the two year designation schedule. EPA generally does not anticipate data from 2006 and 2007 being used in final Pb designations. Under the three year designation schedule, for data collected in 2010, EPA proposed to make the deadline for submission of justifications be May 1, 2011. This is less than a year before the designation decisions would be made, but we believe it is a good compromise between giving a State a reasonable period to prepare the justifications and EPA a reasonable period to consider the information submitted by the State. Similarly, under the two year designation schedule, for data collected in 2009, EPA proposed to make the deadline for submission of justifications be May 1, 2010. Table 5 summarizes the three year designation deadlines in the proposal and discussed in this section, and Table 6 summarizes the two year designation deadlines.

TABLE 5—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN THREE YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	September 15, 2010. *
2007	July 1, 2009 *	September 15, 2010.
2008	July 1, 2009	September 15, 2010. *
2009	July 1, 2010	September 15, 2010. *
2010	May 1, 2011 *	May 1, 2011. *

* Indicates proposed change from generic schedule in 40 CFR 50.14.

TABLE 6—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN TWO YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	September 15, 2009.
2007	July 1, 2009 *	September 15, 2009. *
2008	July 1, 2009	September 15, 2009. *

TABLE 6—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN TWO YEARS—Continued

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2009	May 1, 2010 *	May 1, 2010. *

* Indicates proposed change from generic schedule in 40 CFR 50.14.

EPA invited comment on these proposed changes in the exceptional event flagging and documentation submission deadlines.

B. Comments and Responses

EPA received only one comment on the proposed revision to the schedule for flagging and documenting exceptional event data which could affect Pb designation decisions. The comment from the North Carolina Department of Environment and Natural Resources' (NCDENR) Division of Air Quality (DAQ) stated that: ''NCDAQ believes states need proper time to provide exceptional events documentation before designations are made.''

EPA believes that the final schedule provides states with adequate time for flagging exceptional values and providing documentation to support exceptional event claims. Also, NCDAQ did not specifically state either that the proposed deadlines were inadequate or ask for more time; nor did it provide any alternative schedules for the Agency's consideration.

C. Final

EPA's final schedule for flagging and documenting exceptional event data claims is shown in the tables that follow. Table 7 summarizes the final deadlines for areas where final designations occur no later than October 15, 2011 (i.e., no later than three years after promulgation of a new NAAQS). Table 8 summarizes the final dealines for areas where final desiginations occur no later than October 15, 2010 (i.e., no later than two years after promulgation of a new NAAQS).

TABLE 7—FINAL SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED WITHIN THREE YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	October 15 2010. *
2007	July 1, 2009 *	October 15, 2010.
2008	July 1, 2009	October 15, 2010. *
2009	July 1, 2010	October 15, 2010. *
2010	May 1, 2011 *	May 1, 2011. *

* Indicates change from generic schedule in 40 CFR 50.14.

TABLE 8—FINAL SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED WITHIN TWO YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009 *	October 15, 2009.
2007	July 1, 2009 *	October 15, 2009. *
2008	July 1, 2009	October 15, 2009. *
2009	May 1, 2010 *	May 1, 2010. *

* Indicates change from generic schedule in 40 CFR 50.14.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–OAR–2006–0735). In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. A copy of the analysis is available in the RIA docket (EPA–HQ–OAR–2008–0253) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining four alternative Pb NAAQS nationwide. Specifically, the RIA examines the alternatives of 0.50 μg/m^3, 0.40 μg/m^3, 0.30 μg/m^3, 0.20 μg/m^3, 0.15 μg/m^3 and 0.10 μg/m^3. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve these alternative Pb NAAQS. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising

NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

B. Paperwork Reduction Act

The information collection requirements in this final rule will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). While this final rule amends the requirements for Pb FRM and FEM determinations, they merely provide additional flexibility in meeting the FRM/FEM determination requirements. Furthermore, we do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with Pb FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0559.12). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystem impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for Pb monitoring sites, require the siting and operation of additional Pb ambient air monitors, and the reporting of the collected ambient Pb monitoring data to EPA's Air Quality System (AQS). We have estimated the burden based on the final monitoring requirements of this rule. Based on these requirements, the annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) for 150 respondents is estimated to increase by a total of 22,376 labor hours per year with an increase of $1,910,059 per year. Burden is defined at 5 CFR 1320.3(b).

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 in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

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 Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of Pb in ambient air as required by section 109 of the CAA. *American Trucking Ass'ns* v. *EPA,* 175 F. 3d 1027, 1044–45 (D.C. cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Unless otherwise prohibited by law, under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is required under section 202, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The revisions to the Pb NAAQS impose no enforceable duty on any State, local or tribal governments or the private sector. The expected costs associated with the increased monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed $100 million in the aggregate for any year. Furthermore, as

indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the Pb NAAQS.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the Pb NAAQS. In this final rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

EPA has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, under CAA section 107, the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS or monitoring requirements for NAAQS. Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this action, EPA contacted tribal environmental professionals during the development of this rule. EPA staff participated in the regularly scheduled Tribal Air Call sponsored by the National Tribal Air Association during the spring of 2008 as the proposal was under development, and also offered several informational briefings on the proposal to Tribal environmental professionals in Summer 2008 during the public comment period on the proposed rule. EPA sent individual letters to all federally recognized Tribes within the lower 48 states and Alaska to give Tribal leaders the opportunity for consultation, and EPA staff also participated in Tribal public meetings, such as the National Tribal Forum meeting in June 2008, where Tribes discussed their concerns regarding the proposed rule. EPA received comments from a number of Tribes on the proposed rule; these comments are addressed in the relevant sections of the preamble and Response to Comments for this rulemaking.

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

This action is subject to EO 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by EO 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The final rule establishes uniform national ambient air quality standards for Pb; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because neurological effects in children are among if not the most sensitive health endpoints for Pb exposure. Because children are considered a sensitive population, we have carefully evaluated the environmental health effects of exposure to Pb pollution among children. These effects and the size of the population affected are summarized in chapters 6 and 8 of the Criteria Document and sections 3.3 and 3.4 of the Staff Paper, and the results of our evaluation of the effects of Pb pollution on children are discussed in sections II.B and II.C of the notice of proposed rulemaking, and section II.A of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for Pb. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104–113, § 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 rule involves technical standards. EPA has established low-volume PM_{10} samplers coupled with XRF analysis as the FRM for Pb-PM_{10} measurement. While EPA identified the ISO standard ''Determination of the particulate lead content of aerosols collected on filters'' (ISO 9855: 1993) as being potentially applicable, the final rule does not permit its use. EPA determined that the use of this voluntary consensus standard would be impractical because the analysis method does not provide for the method detection limits necessary to adequately characterize ambient Pb concentrations for the purpose of determining compliance with the revisions to the Pb NAAQS.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The final rule establishes uniform national standards for Pb in ambient air. In the Administrator's judgment, the revised Pb NAAQS protect public health, including the health of sensitive groups, with an adequate margin of safety. As discussed earlier in this preamble (see section II) and in the Response to Comments, the Administrator expressly considered the available information regarding health effects among vulnerable and susceptible populations in making the determination about which standards are requisite.

Some commenters expressed concerns that EPA had failed to adequately assess the environmental justice implications of its proposed decision. These commenters asserted specifically that low-income and minority populations constitute susceptible subpopulations and that the proposed revisions to the primary Pb standards would be insufficient to protect these subpopulations with an adequate margin of safety. In addition, some commenters stated that EPA had failed to adequately evaluate or address the disproportionate adverse impact of Pb exposure on poor and minority populations as required by EO 12898. These commenters assert that in spite of significant scientific evidence indicating that the burden of lead exposure is higher in poor communities and communities of color, EPA has not taken the differing impacts of lead exposure into account in revising the Pb NAAQS.

At the time of proposal, EPA prepared a technical memo to assess the socio-demographic characteristics of populations living near ambient air Pb monitors and stationary sources of Pb emissions (Pekar *et al.*, 2008). Due to limitations in the available data, most significantly limitations on information regarding whether current ambient air concentrations of Pb (as measured by fixed-site monitors or proximity to stationary sources of Pb) are associated with elevated exposure or increased risk for any socio-demographic group, EPA was not able to draw conclusions regarding the impact of Pb air pollution on minority and low-income populations in this analysis [or ''memo'']. However, EPA believes that the newly strengthened Pb standards and the new requirements for ambient air monitoring for Pb will have the greatest benefit in reducing health risks associated with exposure to ambient air Pb in those areas where ambient air concentrations are currently the highest. Thus, to the extent that any population groups, including minorities or low-income populations, are currently experiencing disproportionate exposure to ambient air-related Pb, those groups can be expected to experience relatively greater air quality improvements under the revised standards. Nationwide, these revised, more stringent standards will not have adverse health impacts on any population, including any minority or low-income population.

K. 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 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 a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective January 12, 2009.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 53

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

40 CFR Part 58

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

Dated: October 15, 2008.

Stephen L. Johnson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I of the code of Federal regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter ($PM_{2.5}$) standards contained in §§ 50.7 and 50.13 and lead standards contained in § 50.16 shall be corrected to a reference temperature of 25 (deg) C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ for purposes of comparison to the standards contained in §§ 50.7 and 50.13 and of lead for purposes of comparison to the standards contained in § 50.16 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

■ 3. Section 50.12 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 50.12 National primary and secondary ambient air quality standards for lead.

* * * * *

(b) The standards set forth in this section will remain applicable to all areas notwithstanding the promulgation of lead national ambient air quality standards (NAAQS) in § 50.16. The lead NAAQS set forth in this section will no longer apply to an area one year after the effective date of the designation of that area, pursuant to section 107 of the Clean Air Act, for the lead NAAQS set forth in § 50.16; except that for areas designated nonattainment for the lead NAAQS set forth in this section as of the effective date of § 50.16, the lead NAAQS set forth in this section will apply until that area submits, pursuant to section 191 of the Clean Air Act, and EPA approves, an implementation plan providing for attainment and/or maintenance of the lead NAAQS set forth in § 50.16.

■ 4. Section 50.14 is amended by:

■ a. Revising paragraph (a)(2);

■ b. Revising paragraph (c)(2)(iii);

■ c. Redesignating paragraph (c)(2)(v) as paragraph (c)(2)(vi) and adding a new paragraph (c)(2)(v); and

■ d. Redesignating existing paragraphs (c)(3)(iii) and (c)(3)(iv) as paragraphs (c)(3)(iv) and (c)(3)(v), respectively, and adding a new paragraph (c)(3)(iii).

The additions and revisions read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

(a) * * *

(2) Demonstration to justify data exclusion may include any reliable and accurate data, but must demonstrate a clear causal relationship between the measured exceedance or violation of such standard and the event in accordance with paragraph (c)(3)(iv) of this section.

* * * * *

(c) * * *

(2) * * *

(iii) Flags placed on data as being due to an exceptional event together with an initial description of the event shall be submitted to EPA not later than July 1st of the calendar year following the year in which the flagged measurement occurred, except as allowed under paragraph (c)(2)(iv) or (c)(2)(v) of this section.

* * * * *

(v) For lead (Pb) data collected during calendar years 2006–2008, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2009. For Pb data collected during calendar year 2009, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2010. For Pb data collected during calendar year 2010, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than May 1, 2011.

* * * * *

(3) * * *

(iii) A State that flags Pb data collected during calendar years 2006–2009, pursuant to paragraph (c)(2)(v) of this section shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify exclusion of the data not later than October 15, 2010. A State that flags Pb data collected during calendar year 2010 shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify the exclusion of the data not later than May 1, 2011. A state must submit the public comments it received along with its demonstration to EPA.

* * * * *

■ 5. Section 50.16 is added to read as follows:

§ 50.16 National primary and secondary ambient air quality standards for lead.

(a) The national primary and secondary ambient air quality standards for lead (Pb) and its compounds are 0.15 micrograms per cubic meter, arithmetic mean concentration over a 3-month period, measured in the ambient air as Pb either by:

(1) A reference method based on Appendix G of this part and designated in accordance with part 53 of this chapter or;

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The national primary and secondary ambient air quality standards for Pb are met when the maximum arithmetic 3-month mean concentration for a 3-year period, as determined in accordance with Appendix R of this part, is less than or equal to 0.15 micrograms per cubic meter.

■ 6. Appendix G is amended as follows:

■ a. In section 10.2 the definition of the term ''V_{STP}'' in the equation is revised,

■ b. In section 14 reference 10 is added and reference 15 is revised:

Appendix G to Part 50—Reference Method for the Determination of Lead in Suspended Particulate Matter Collected From Ambient Air

* * * * *

10.2 * * *

V_{STP} = Air volume from section 10.1.

* * * * *

14. * * *

10. Intersociety Committee (1972). Methods of Air Sampling and Analysis. 1015 Eighteenth Street, N.W. Washington, D.C.: American Public Health Association. 365–372. * * *

15. Sharon J. Long, et al., ''Lead Analysis of Ambient Air Particulates: Interlaboratory Evaluation of EPA Lead Reference Method'' APCA Journal, 29, 28–31 (1979).

* * * * *

■ 7. Appendix Q is added to read as follows:

Appendix Q to Part 50—Reference Method for the Determination of Lead in Particulate Matter as PM_{10} Collected From Ambient Air

This Federal Reference Method (FRM) draws heavily from the specific analytical protocols used by the U.S. EPA.

1. *Applicability and Principle*

1.1 This method provides for the measurement of the lead (Pb) concentration in particulate matter that is 10 micrometers or less (PM_{10}) in ambient air. PM_{10} is collected on an acceptable (see section 6.1.2) 46.2 mm diameter polytetrafluoroethylene (PTFE) filter for 24 hours using active sampling at local conditions with a low-volume air sampler. The low-volume sampler has an average flow rate of 16.7 liters per minute (Lpm) and total sampled volume of 24 cubic meters (m^3) of air. The analysis of Pb in PM_{10} is performed on each individual 24-hour sample. Gravimetric mass analysis of PM_{10c} filters is not required for Pb analysis. For the purpose of this method, PM_{10} is defined as particulate matter having an aerodynamic diameter in the nominal range of 10 micrometers (10 µm) or less.

1.2 For this reference method, PM_{10} shall be collected with the PM_{10c} federal reference method (FRM) sampler as described in Appendix O to Part 50 using the same sample period, measurement procedures, and requirements specified in Appendix L of Part 50. The PM_{10c} sampler is also being used for measurement of $PM_{10-2.5}$ mass by difference and as such, the PM_{10c} sampler must also meet all of the performance requirements specified for $PM_{2.5}$ in Appendix L. The concentration of Pb in the atmosphere is determined in the total volume of air sampled and expressed in micrograms per cubic meter (µg/m^3) at local temperature and pressure conditions.

1.3 The FRM will serve as the basis for approving Federal Equivalent Methods (FEMs) as specified in 40 CFR Part 53 (Reference and Equivalent Methods). This FRM specifically applies to the analysis of Pb in PM_{10} filters collected with the PM_{10c} sampler. If these filters are analyzed for elements other than Pb, then refer to the guidance provided in the EPA Inorganic Compendium Method IO–3.3 (Reference 1 of section 8) for multi-element analysis.

1.4 The PM_{10c} air sampler draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator, where the suspended particulate matter in the PM_{10} size range is separated for collection on a PTFE filter over the specified sampling period. The Pb content of the PM_{10} sample is analyzed by energy-dispersive X-ray fluorescence spectrometry (EDXRF). Energy-dispersive X-ray fluorescence spectrometry provides a means for identification of an element by measurement of its characteristic X-ray emission energy. The method allows for quantification of the element by measuring the intensity of X-rays emitted at the characteristic photon energy and then relating this intensity to the elemental concentration. The number or intensity of X-rays produced at a given energy provides a measure of the amount of the element present by comparisons with calibration standards. The X-rays are detected and the spectral signals are acquired and processed with a personal computer. EDXRF is commonly used as a non-destructive method for quantifying trace elements in PM. A detailed explanation of quantitative X-ray spectrometry is described in references 2, 3 and 4.

1.5 Quality assurance (QA) procedures for the collection of monitoring data are contained in Part 58, Appendix A.

2. *PM_{10} Pb Measurement Range and Detection Limit.* The values given below in section 2.1 and 2.2 are typical of the method capabilities. Absolute values will vary for individual situations depending on the instrument, detector age, and operating conditions used. Data are typically reported in ng/m^3 for ambient air samples; however, for this reference method, data will be reported in µg/m^3 at local temperature and pressure conditions.

2.1 *EDXRF Pb Measurement Range.* The typical ambient air measurement range is 0.001 to 30 µg Pb/m^3, assuming an upper range calibration standard of about 60 µg Pb per square centimeter (cm^2), a filter deposit area of 11.86 cm^2, and an air volume of 24 m^3. The top range of the EDXRF instrument is much greater than what is stated here. The top measurement range of quantification is defined by the level of the high concentration calibration standard used and can be increased to expand the measurement range as needed.

2.2 *Detection Limit (DL).* A typical estimate of the one-sigma detection limit (DL) is about 2 ng Pb/cm^2 or 0.001 µg Pb/m^3, assuming a filter size of 46.2 mm (filter deposit area of 11.86 cm^2) and a sample air volume of 24 m^3. The DL is an estimate of the lowest amount of Pb that can be reliably distinguished from a blank filter. The one-sigma detection limit for Pb is calculated as the average overall uncertainty or propagated error for Pb, determined from measurements on a series of blank filters from the filter lot(s) in use. Detection limits must be determined for each filter lot in use. If a new filter lot is used, then a new DL must be determined. The sources of random error which are considered are calibration uncertainty; system stability; peak and background counting statistics; uncertainty in attenuation corrections; and uncertainty in peak overlap corrections, but the dominating source by far is peak and background counting statistics. At a minimum, laboratories are to determine annual estimates of the DL using the guidance provided in Reference 5.

3. *Factors Affecting Bias and Precision of Lead Determination by EDXRF*

3.1 *Filter Deposit.* X-ray spectra are subject to distortion if unusually heavy deposits are analyzed. This is the result of internal absorption of both primary and secondary X-rays within the sample; however, this is not an issue for Pb due to the energetic X-rays used to fluoresce Pb and the energetic characteristic X-rays emitted by Pb. The optimum mass filter loading for multi-elemental EDXRF analyis is about 100 µg/cm^2 or 1.2 mg/filter for a 46.2-mm filter. Too little deposit material can also be problematic due to low counting statistics and signal noise. The particle mass deposit should minimally be 15 µg/cm^2. The maximum PM_{10} filter loading or upper concentration limit of mass expected to be collected by the PM_{10c} sampler is 200 µg/m^3 (Appendix O to Part 50, Section 3.2). This equates to a mass loading of about 400 µg/cm^2 and is the maximum expected loading for PM_{10c} filters. This maximum loading is acceptable for the analysis of Pb and other high-Z elements with very energetic characteristic X-rays. A properly collected sample will have a uniform deposit over the entire collection area. Samples with physical deformities (including a visually non-

uniform deposit area) should not be quantitatively analyzed. Tests on the uniformity of particle deposition on PM_{10C} filters showed that the non-uniformity of the filter deposit represents a small fraction of the overall uncertainty in ambient Pb concentration measurement. The analysis beam of the XRF analyzer does not cover the entire filter collection area. The minimum allowable beam size is 10 mm.

3.2 *Spectral Interferences and Spectral Overlap.* Spectral interference occurs when the entirety of the analyte spectral lines of two species are nearly 100% overlapped. The presence of arsenic (As) is a problematic interference for EDXRF systems which use the Pb L_α line exclusively to quantify the Pb concentration. This is because the Pb L_α line and the As K_α lines severely overlap. The use of multiple Pb lines, including the L_β and/or the L_γ lines for quantification must be used to reduce the uncertainty in the Pb determination in the presence of As. There can be instances when lines partially overlap the Pb spectral lines, but with the energy resolution of most detectors these overlaps are typically de-convoluted using standard spectral de-convolution software provided by the instrument vendor. An EDXRF protocol for Pb must define which Pb lines are used for quantification and where spectral overlaps occur. A de-convolution protocol must be used to separate all the lines which overlap with Pb.

3.3 *Particle Size Effects and Attenuation Correction Factors.* X-ray attenuation is dependent on the X-ray energy, mass sample loading, composition, and particle size. In some cases, the excitation and fluorescent X-rays are attenuated as they pass through the sample. In order to relate the measured intensity of the X-rays to the thin-film calibration standards used, the magnitude of any attenuation present must be corrected for. See references 6, 7, and 8 for more discussion on this issue. Essentially no attenuation corrections are necessary for Pb in PM_{10}: Both the incoming excitation X-rays used for analyzing lead and the fluoresced Pb X-rays are sufficiently energetic that for particles in this size range and for normal filter loadings, the Pb X-ray yield is not significantly impacted by attenuation.

4. *Precision*

4.1 Measurement system precision is assessed according to the procedures set forth in Appendix A to part 58. Measurement method precision is assessed from collocated sampling and analysis. The goal for acceptable measurement uncertainty, as precision, is defined as an upper 90 percent confidence limit for the coefficient of variation (CV) of 20 percent.

5. *Bias*

5.1 Measurement system bias for monitoring data is assessed according to the procedures set forth in Appendix A of part 58. The bias is assessed through an audit using spiked filters. The goal for measurement bias is defined as an upper 95 percent confidence limit for the absolute bias of 15 percent.

6. *Measurement of PTFE Filters by EDXRF*

6.1 *Sampling*

6.1.1 *Low-Volume PM_{10c} Sampler.* The low-volume PM_{10c} sampler shall be used for PM_{10} sample collection and operated in accordance with the performance specifications described in Part 50, Appendix L.

6.1.2 *PTFE Filters and Filter Acceptance Testing.* The PTFE filters used for PM_{10c} sample collection shall meet the specifications provided in Part 50, Appendix L. The following requirements are similar to those currently specified for the acceptance of $PM_{2.5}$ filters that are tested for trace elements by EDXRF. For large filter lots (greater than 500 filters) randomly select 20 filters from a given lot. For small lots (less than 500 filters) a lesser number of filters may be taken. Analyze each blank filter separately and calculate the average lead concentration in ng/cm^2. Ninety percent, or 18 of the 20 filters, must have an average lead concentration that is less than 4.8 ng Pb/cm^2.

6.1.2.1 *Filter Blanks.* Field blank filters shall be collected along with routine samples. Field blank filters will be collected that are transported to the sampling site and placed in the sampler for the duration of sampling without sampling. Laboratory blank filters from each filter lot used shall be analyzed with each batch of routine sample filters analyzed. Laboratory blank filters are used in background subtraction as discussed below in Section 6.2.4.

6.2 *Analysis.* The four main categories of random and systematic error encountered in X-ray fluorescence analysis include errors from sample collection, the X-ray source, the counting process, and inter-element effects. These errors are addressed through the calibration process and mathematical corrections in the instrument software. Spectral processing methods are well established and most commercial analyzers have software that can implement the most common approaches (references 9–11) to background subtraction, peak overlap correction, counting and deadtime corrections.

6.2.1 *EDXRF Analysis Instrument.* An energy-dispersive XRF system is used. Energy-dispersive XRF systems are available from a number of commercial vendors. Examples include Thermo (*www.thermo.com*), Spectro (*http://www.spectro.com*), Xenemetrix (*http://www.xenemetrix.com*) and PANalytical (*http://www.panalytical.com*).[1] The analysis is performed at room temperature in either vacuum or in a helium atmosphere. The specific details of the corrections and calibration algorithms are typically included in commercial analytical instrument software routines for automated spectral acquisition and processing and vary by manufacturer. It is important for the analyst to understand the correction procedures and algorithms of the particular system used, to ensure that the necessary corrections are applied.

6.2.2 *Thin film standards.* Thin film standards are used for calibration because they most closely resemble the layer of particles on a filter. Thin films standards are typically deposited on Nuclepore substrates. The preparation of thin film standards is discussed in reference 8, and 10. The NIST SRM 2783 (Air Particulate on Filter Media) is currently available on polycarbonate filters and contains a certified concentration for Pb. Thin film standards at 15 and 50 μg/cm^2 are commercially available from MicroMatter Inc. (Arlington, WA).

6.2.3 *Filter Preparation.* Filters used for sample collection are 46.2-mm PTFE filters with a pore size of 2 microns and filter deposit area 11.86 cm^2. Cold storage is not a requirement for filters analyzed for Pb; however, if filters scheduled for XRF analysis were stored cold, they must be allowed to reach room temperature prior to analysis. All filter samples received for analysis are checked for any holes, tears, or a non-uniform deposit which would prevent quantitative analysis. Samples with physical deformities are not quantitatively analyzable. The filters are carefully removed with tweezers from the Petri dish and securely placed into the instrument-specific sampler holder for analysis. Care must be taken to protect filters from contamination prior to analysis. Filters must be kept covered when not being analyzed. No other preparation of filter samples is required.

6.2.4 *Calibration.* In general, calibration determines each element's sensitivity, *i.e.*, its response in x-ray counts/sec to each μg/cm^2 of a standard and an interference coefficient for each element that causes interference with another one (See section 3.2 above). The sensitivity can be determined by a linear plot of count rate versus concentration (μg/cm^2) in which the slope is the instrument's sensitivity for that element. A more precise way, which requires fewer standards, is to fit sensitivity versus atomic number. Calibration is a complex task in the operation of an XRF system. Two major functions accomplished by calibration are the production of reference spectra which are used for fitting and the determination of the elemental sensitivities. Included in the reference spectra (referred to as ''shapes'') are background-subtracted peak shapes of the elements to be analyzed (as well as interfering elements) and spectral backgrounds. Pure element thin film standards are used for the element peak shapes and clean filter blanks from the same lot as routine filter samples are used for the background. The analysis of Pb in PM filter deposits is based on the assumption that the thickness of the deposit is small with respect to the characteristic Pb X-ray transmission thickness. Therefore, the concentration of Pb in a sample is determined by first calibrating the spectrometer with thin film standards to determine the sensitivity factor for Pb and then analyzing the unknown samples under identical excitation conditions as used to determine the calibration. Calibration shall be performed annually or when significant repairs or changes occur (e.g., a change in fluorescers, X-ray tubes, or detector). Calibration establishes the elemental sensitivity factors and the magnitude of interference or overlap coefficients. *See* reference 7 for more detailed discussion of calibration and analysis of shapes standards for background correction, coarse particle absorption corrections, and spectral overlap.

6.2.4.1 *Spectral Peak Fitting.* The EPA uses a library of pure element peak shapes

[1] These are examples of available systems and is not an all inclusive list. The mention of commercial products does not imply endorsement by the U.S. Environmental Protection Agency.

(shape standards) to extract the elemental background-free peak areas from an unknown spectrum. It is also possible to fit spectra using peak stripping or analytically defined functions such as modified Gaussian functions. The EPA shape standards are generated from pure, mono-elemental thin film standards. The shape standards are acquired for sufficiently long times to provide a large number of counts in the peaks of interest. It is not necessary for the concentration of the standard to be known. A slight contaminant in the region of interest in a shape standard can have a significant and serious effect on the ability of the least squares fitting algorithm to fit the shapes to the unknown spectrum. It is these elemental peak shapes that are fitted to the peaks in an unknown sample during spectral processing by the analyzer. In addition to this library of elemental shapes there is also a background shape spectrum for the filter type used as discussed below in section 6.2.4.2 of this section.

6.2.4.2 *Background Measurement and Correction.* A background spectrum generated by the filter itself must be subtracted from the X-ray spectrum prior to extracting peak areas. Background spectra must be obtained for each filter lot used for sample collection. The background shape standards which are used for background fitting are created at the time of calibration. If a new lot of filters is used, new background spectra must be obtained. A minimum of 20 clean blank filters from each filter lot are kept in a sealed container and are used exclusively for background measurement and correction. The spectra acquired on individual blank filters are added together to produce a single spectrum for each of the secondary targets or fluorescers used in the analysis of lead. Individual blank filter spectra which show atypical contamination are excluded from the summed spectra. The summed spectra are fitted to the appropriate background during spectral processing. Background correction is automatically included during spectral processing of each sample.

7. *Calculation.*

7.1 *PM_{10} Pb concentrations.* The PM_{10} Pb concentration in the atmosphere (μg/m³) is calculated using the following equation:

$$M_{Pb} = \frac{C_{Pb} \times A}{V_{LC}}$$

Where,

M_{Pb} is the mass per unit volume for lead in μg/m³;

C_{Pb} is the mass per unit area for lead in μg/cm² as measured by XRF;

A is the filter deposit area in cm²;

V_{LC} is the total volume of air sampled by the PM_{10c} sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler in m³.

7.2 *PM_{10} Pb Uncertainty Calculations.* The principal contributors to total uncertainty of XRF values include: field sampling; filter deposit area; XRF calibration; attenuation or loss of the x-ray signals due to the other components of the particulate sample; and determination of the Pb X-ray emission peak area by curve fitting. See reference 12 for a detailed discussion of how uncertainties are similarly calculated for the $PM_{2.5}$ Chemical Speciation program.

The model for calculating total uncertainty is:

$$\delta_{tot} = (\delta_f^2 + \delta_a^2 + \delta_c^2 + \delta_v^2)^{1/2}$$

Where,

δ_f = fitting uncertainty (XRF-specific, from 2 to 100+%)

δ_a = attenuation uncertainty (XRF-specific, insignificant for Pb)

δ_c = calibration uncertainty (combined lab uncertainty, assumed as 5%)

δ_v = volume/deposition size uncertainty (combined field uncertainty, assumed as 5%)

8. *References*

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■ 8. Appendix R is added to read as follows:

Appendix R to Part 50—Interpretation of the National Ambient Air Quality Standards for Lead

1. General.

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary and secondary national ambient air quality standards (NAAQS) for lead (Pb) specified in § 50.16 are met. The NAAQS indicator for Pb is defined as: lead and its compounds, measured as elemental lead in total suspended particulate (Pb-TSP), sampled and analyzed by a Federal reference method (FRM) based on appendix G to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Although Pb-TSP is the lead NAAQS indicator, surrogate Pb-TSP concentrations shall also be used for NAAQS comparisons; specifically, valid surrogate Pb-TSP data are concentration data for lead and its compounds, measured as elemental lead, in particles with an aerodynamic size of 10 microns or less (Pb-PM_{10}), sampled and analyzed by an FRM based on appendix Q to this part or by an FEM designated in accordance with part 53 of this chapter. Surrogate Pb-TSP data (i.e., Pb-PM_{10} data), however, can only be used to show that the Pb NAAQS were violated (i.e., not met); they can not be used to demonstrate that the Pb NAAQS were met. Pb-PM_{10} data used as surrogate Pb-TSP data shall be processed at face value; that is, without any transformation or scaling. Data handling and computation procedures to be used in making comparisons between reported and/or surrogate Pb-TSP concentrations and the level of the Pb NAAQS are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in §§ 50.1, 50.14, and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual monitoring network plan refers to the plan required by section 58.10 of this chapter.

Creditable samples are samples that are given credit for data completeness. They include valid samples collected on required sampling days and valid ''make-up'' samples taken for missed or invalidated samples on required sampling days.

Daily values for Pb refer to the 24-hour mean concentrations of Pb (Pb-TSP or Pb-PM_{10}), measured from midnight to midnight (local standard time), that are used in NAAQS computations.

Design value is the site-level metric (i.e., statistic) that is compared to the NAAQS level to determine compliance; the design value for the Pb NAAQS is selected according to the procedures in this appendix from among the valid three-month Pb-TSP and surrogate Pb-TSP (Pb-PM_{10}) arithmetic mean concentration for the 38-month period consisting of the most recent 3-year calendar period plus two previous months (i.e., 36 3-month periods) using the last month of each 3-month period as the period of report.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that can not be used as ''make-up samples'' for missed or invalidated scheduled samples. Extra samples are used in mean calculations. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and Pb-PM_{10} data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Make-up samples are samples taken to replace missed or invalidated required scheduled samples. Make-ups can be made by either the primary or collocated (same size fraction) instruments; to be considered a valid make-up, the sampling must be conducted with equipment and procedures that meet the requirements for scheduled sampling. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day. Make-up samples can not span years; that is, if a scheduled sample for December is missed (or voided), it can not be made up in January. Make-up samples, however, may span months, for example a missed sample on January 31 may be made up on February 1, 2, 3, 4, 5, or 7 (with an assumed sampling frequency of every sixth day). Section 3(e) explains how such month-spanning make-up samples are to be treated for purposes of data completeness and mean calculations. Only two make-up samples are permitted each calendar month; these are counted according to the month in which the miss and not the makeup occurred. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and Pb-PM_{10} data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Monthly mean refers to an arithmetic mean, calculated as specified in section 6(a) of this appendix. Monthly means are computed at each monitoring site separately for Pb-TSP and Pb-PM_{10} (i.e., by site-parameter-year-month).

Parameter refers either to Pb-TSP or to Pb-PM_{10}.

Pollutant Occurrence Code (POC) refers to a numerical code (1, 2, 3, etc.) used to distinguish the data from two or more monitors for the same parameter at a single monitoring site.

Scheduled sampling day means a day on which sampling is scheduled based on the required sampling frequency for the monitoring site, as provided in section 58.12 of this chapter.

Three-month means are arithmetic averages of three consecutive monthly means. Three-month means are computed on a rolling, overlapping basis. Each distinct monthly mean will be included in three different 3-month means; for example, in a given year, a November mean would be included in: (1) The September-October-November 3-month mean, (2) the October-November-December 3-month mean, and (3) the November-December-January(of the following year) 3-month mean. Three-month means are computed separately for each parameter per section 6(a) (and are referred to as 3-month parameter means) and are validated according to the criteria specified in section 4(c). The parameter-specific 3-month means are then prioritized according to section 2(a) to determine a single 3-month site mean.

Year refers to a calendar year.

2. *Use of Pb-PM_{10} Data as Surrogate Pb-TSP Data.*

(a) As stipulated in section 2.10 of Appendix C to 40 CFR part 58, at some mandatory Pb monitoring locations, monitoring agencies are required to sample for Pb as Pb-TSP, and at other mandatory Pb monitoring sites, monitoring agencies are permitted to monitor for Pb-PM_{10} in lieu of Pb-TSP. In either situation, valid collocated Pb data for the other parameter may be produced. Additionally, there may be non-required monitoring locations that also produce valid Pb-TSP and/or valid Pb-PM_{10} data. Pb-TSP data and Pb-PM_{10} data are always processed separately when computing monthly and 3-month parameter means; monthly and 3-month parameter means are validated according to the criteria stated in section 4 of this appendix. Three-month ''site'' means, which are the final valid 3-month mean from which a design value is identified, are determined from the one or two available valid 3-month parameter means according to the following prioritization which applies to all Pb monitoring locations.

(i) Whenever a valid 3-month Pb-PM_{10} mean shows a violation and either is greater than a corresponding (collocated) 3-month Pb-TSP mean or there is no corresponding valid 3-month Pb-TSP mean present, then that 3-month Pb-PM_{10} mean will be the site-level mean for that (site's) 3-month period.

(ii) Otherwise (i.e., there is no valid violating 3-month Pb-PM_{10} that exceeds a corresponding 3-month Pb-TSP mean),

(A) If a valid 3-month Pb-TSP mean exists, then it will be the site-level mean for that (site's) 3-month period, or

(B) If a valid 3-month Pb-TSP mean does not exist, then there is no valid 3-month site mean for that period (even if a valid non-violating 3-month Pb-PM_{10} mean exists).

(b) As noted in section 1(a) of this appendix, FRM/FEM Pb-PM_{10} data will be processed at face value (i.e., at reported concentrations) without adjustment when computing means and making NAAQS comparisons.

3. *Requirements for Data Used for Comparisons With the Pb NAAQS and Data Reporting Considerations.*

(a) All valid FRM/FEM Pb-TSP data and all valid FRM/FEM Pb-PM_{10} data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Pb-TSP and Pb-PM_{10} data representing sample collection periods prior to January 1, 2009 (i.e., ''pre-rule'' data) will also be considered valid for NAAQS comparisons and related attainment/nonattainment determinations if the sampling and analysis methods that were utilized to collect that data were consistent with previous or newly designated FRMs or FEMs and with either the provisions of part 58 of this chapter including appendices A, C, and E that were in effect at the time of original sampling or that are in effect at the time of the attainment/nonattainment determination, and if such data are submitted to AQS prior to September 1, 2009.

(b) Pb-TSP and Pb-PM_{10} measurement data are reported to AQS in units of micrograms per cubic meter ($\mu g/m^3$) at local conditions (local temperature and pressure, LC) to three decimal places; any additional digits to the right of the third decimal place are truncated. Pre-rule Pb-TSP and Pb-PM_{10} concentration data that were reported in standard conditions (standard temperature and standard pressure, STP) will not require a conversion to local conditions but rather, after truncating to three decimal places and processing as stated in this appendix, shall be compared ''as is'' to the NAAQS (i.e., the LC to STP conversion factor will be assumed to be one). However, if the monitoring agency has retroactively resubmitted Pb-TSP or Pb-PM_{10} pre-rule data converted from STP to LC based on suitable meteorological data, only the LC data will be used.

(c) At each monitoring location (site), Pb-TSP and Pb-PM_{10} data are to be processed separately when selecting daily data by day (as specified in section 3(d) of this appendix), when aggregating daily data by month (per section 6(a)), and when forming 3-month means (per section 6(b)). However, when deriving (i.e., identifying) the design value for the 38-month period, 3-month means for the two data types may be considered together; see sections 2(a) and 4(e) of this appendix for details.

(d) Daily values for sites will be selected for a site on a size cut (Pb-TSP or Pb-PM_{10}, i.e., ''parameter'') basis; Pb-TSP concentrations and Pb-PM_{10} concentrations shall not be commingled in these determinations. Site level, parameter-specific daily values will be selected as follows:

(i) The starting dataset for a site-parameter shall consist of the measured daily concentrations recorded from the designated primary FRM/FEM monitor for that parameter. The primary monitor for each parameter shall be designated in the appropriate state or local agency annual Monitoring Network Plan. If no primary monitor is designated, the Administrator will select which monitor to treat as primary. All daily values produced by the primary sampler are considered part of the site-parameter data record (i.e., that site-parameter's set of daily values); this includes all creditable samples and all extra samples. For pre-rule Pb-TSP and Pb-PM_{10} data, valid data records present in AQS for the monitor with the lowest occurring Pollutant Occurrence Code (POC), as selected on a site-parameter-daily basis, will constitute the site-

parameter data record. Where pre-rule Pb-TSP data (or subsequent non-required Pb-TSP or Pb-PM_{10} data) are reported in ''composite'' form (i.e., multiple filters for a month of sampling that are analyzed together), the composite concentration will be used as the site-parameter monthly mean concentration if there are no valid daily Pb-TSP data reported for that month with a lower POC.

(ii) Data for the primary monitor for each parameter shall be augmented as much as possible with data from collocated (same parameter) FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular day (scheduled or otherwise), but a valid sample is generated by a collocated (same parameter) FRM/FEM instrument, then that collocated value shall be considered part of the site-parameter data record (i.e., that site-parameter's monthly set of daily values). If more than one valid collocated FRM/FEM value is available, the mean of those valid collocated values shall be used as the daily value. Note that this step will not be necessary for pre-rule data given the daily identification presumption for the primary monitor.

(e) All daily values in the composite site-parameter record are used in monthly mean calculations. However, not all daily values are given credit towards data completeness requirements. Only ''creditable'' samples are given credit for data completeness. Creditable samples include valid samples on scheduled sampling days and valid make-up samples. All other types of daily values are referred to as ''extra'' samples. Make-up samples taken in the (first week of the) month after the one in which the miss/void occurred will be credited for data capture in the month of the miss/void but will be included in the month actually taken when computing monthly means. For example, if a make-up sample was taken in February to replace a missed sample scheduled for January, the make-up concentration would be included in the February monthly mean but the sample credited in the January data capture rate.

4. *Comparisons With the Pb NAAQS.*

(a) The Pb NAAQS is met at a monitoring site when the identified design value is valid and less than or equal to 0.15 micrograms per cubic meter ($\mu g/m^3$). A Pb design value that meets the NAAQS (i.e., 0.15 $\mu g/m^3$ or less), is considered valid if it encompasses 36 consecutive valid 3-month site means (specifically for a 3-year calendar period and the two previous months). For sites that begin monitoring Pb after this rule is effective but before January 15, 2010 (or January 15, 2011), a 2010–2012 (or 2011–2013) Pb design value that meets the NAAQS will be considered valid if it encompasses at least 34 consecutive valid 3-month means (specifically encompassing only the 3-year calendar period). See 4(c) of this appendix for the description of a valid 3-month mean and section 6(d) for the definition of the design value.

(b) The Pb NAAQS is violated at a monitoring site when the identified design value is valid and is greater than 0.15 $\mu g/m^3$, no matter whether determined from Pb-TSP or Pb-PM_{10} data. A Pb design value greater than 0.15 $\mu g/m^3$ is valid no matter how many valid 3-month means in the 3-year period it encompasses; that is, a violating design value is valid even if it (i.e., the highest 3-month mean) is the only valid 3-month mean in the 3-year timeframe. Further, a site does not have to monitor for three full calendar years in order to have a valid violating design value; a site could monitor just three months and still produce a valid (violating) design value.

(c)(i) A 3-month parameter mean is considered valid (i.e., meets data completeness requirements) if the average of the data capture rate of the three constituent monthly means (i.e., the 3-month data capture rate) is greater than or equal to 75 percent. Monthly data capture rates (expressed as a percentage) are specifically calculated as the number of creditable samples for the month (including any make-up samples taken the subsequent month for missed samples in the month in question, and excluding any make-up samples taken in the month in question for missed samples in the previous month) divided by the number of scheduled samples for the month, the result then multiplied by 100 but not rounded. The 3-month data capture rate is the sum of the three corresponding unrounded monthly data capture rates divided by three and the result rounded to the nearest integer (zero decimal places). As noted in section 3(c), Pb-TSP and Pb-PM_{10} daily values are processed separately when calculating monthly means and data capture rates; a Pb-TSP value cannot be used as a make-up for a missing Pb-PM_{10} value or vice versa. For purposes of assessing data capture, Pb-TSP and Pb-PM_{10} data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

(ii) A 3-month parameter mean that does not have at least 75 percent data capture and thus is not considered valid under 4(c)(i) shall be considered valid (and complete) if it passes either of the two following ''data substitution'' tests, one such test for validating an above NAAQS-level (i.e., violating) 3-month Pb-TSP or Pb-PM_{10} mean (using actual ''low'' reported values from the same site at about the same time of the year (i.e., in the same month) looking across three or four years), and the second test for validating a below-NAAQS level 3-month Pb-TSP mean (using actual ''high'' values reported for the same site at about the same time of the year (i.e., in the same month) looking across three or four years). Note that both tests are merely diagnostic in nature intending to confirm that there is a very high likelihood if not certainty that the original mean (the one with less than 75% data capture) reflects the true over/under NAAQS-level status for that 3-month period; the result of one of these data substitution tests (i.e., a ''test mean'', as defined in section 4(c)(ii)(A) or 4(c)(ii)(B)) is not considered the actual 3-month parameter mean and shall not be used in the determination of design values. For both types of data substitution, substitution is permitted only if there are available data points from which to identify the high or low 3-year month-specific values, specifically if there are at least 10 data points total from at least two of the three (or four for November and December) possible year-months. Data substitution may only use data of the same parameter type.

(A) The ''above NAAQS level'' test is as follows: Data substitution will be done in each month of the 3-month period that has less than 75 percent data capture; monthly capture rates are temporarily rounded to integers (zero decimals) for this evaluation. If by substituting the lowest reported daily value for that month (year non-specific; e.g., for January) over the 38-month design value period in question for missing scheduled data in the deficient months (substituting only enough to meet the 75 percent data capture minimum), the computation yields a recalculated test 3-month parameter mean concentration above the level of the standard, then the 3-month period is deemed to have passed the diagnostic test and the level of the standard is deemed to have been exceeded in that 3-month period. As noted in section 4(c)(ii), in such a case, the 3-month parameter mean of the data actually reported, not the recalculated (''test'') result including the low values, shall be used to determine the design value.

(B) The ''below NAAQS level'' test is as follows: Data substitution will be performed for each month of the 3-month period that has less than 75 percent but at least 50 percent data capture; if any month has less than 50% data capture then the 3-month mean can not utilize this substitution test. Also, incomplete 3-month Pb-PM_{10} means can not utilize this test. A 3-month Pb-TSP mean with less than 75% data capture shall still be considered valid (and complete) if, by substituting the highest reported daily value, month-specific, over the 3-year design value period in question, for all missing scheduled data in the deficient months (i.e., bringing the data capture rate up to 100%), the computation yields a recalculated 3-month parameter mean concentration equal or less than the level of the standard (0.15 $\mu g/m^3$), then the 3-month mean is deemed to have passed the diagnostic test and the level of the standard is deemed not to have been exceeded in that 3-month period (for that parameter). As noted in section 4(c)(ii), in such a case, the 3-month parameter mean of the data actually reported, not the recalculated (''test'') result including the high values, shall be used to determine the design value.

(d) Months that do not meet the completeness criteria stated in 4(c)(i) or 4(c)(ii), and design values that do not meet the completeness criteria stated in 4(a) or 4(b), may also be considered valid (and complete) with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The site-level design value for a 38-month period (three calendar years plus two previous months) is identified from the available (between one and 36) valid 3-month site means. In a situation where there are valid 3-month means for both parameters

(Pb-TSP and Pb-PM_{10}), the mean originating from the reported Pb-TSP data will be the one deemed the site-level monthly mean and used in design value identifications unless the Pb-PM_{10} mean shows a violation of the NAAQS and exceeds the Pb-TSP mean; see section 2(a) for details. A monitoring site will have only one site-level 3-month mean per 3-month period; however, the set of site-level 3-month means considered for design value identification (i.e., one to 36 site-level 3-month means) can be a combination of Pb-TSP and Pb-PM_{10} data.

(f) The procedures for calculating monthly means and 3-month means, and identifying Pb design values are given in section 6 of this appendix.

5. *Rounding Conventions.*

(a) Monthly means and monthly data capture rates are not rounded.

(b) Three-month means shall be rounded to the nearest hundredth μg/m³ (0.xx). Decimals 0.xx5 and greater are rounded up, and any decimal lower than 0.xx5 is rounded down. E.g., a 3-month mean of 0.104925 rounds to 0.10 and a 3-month mean of .10500 rounds to 0.11. Three-month data capture rates, expressed as a percent, are round to zero decimal places.

(c) Because a Pb design value is simply a (highest) 3-month mean and because the NAAQS level is stated to two decimal places, no additional rounding beyond what is specified for 3-month means is required before a design value is compared to the NAAQS.

6. *Procedures and Equations for the Pb NAAQS.*

(a)(i) A monthly mean value for Pb-TSP (or Pb-PM_{10}) is determined by averaging the daily values of a calendar month using equation 1 of this appendix, unless the Administrator chooses to exercise his discretion to use the alternate approach described in 6(a)(ii).

Equation 1

$$\bar{X}_{m,y,s} = \frac{1}{n_m}\sum_{i=1}^{n_m} X_{i,m,y,s}$$

Where:

$X_{m,y,s}$ = the mean for month m of the year y for sites; and

n_m = the number of daily values in the month (creditable plus extra samples); and

$X_{i,m,y,s}$ = the ith value in month m for year y for site s.

(a)(ii) The Administrator may at his discretion use the following alternate approach to calculating the monthly mean concentration if the number of extra sampling days during a month is greater than the number of successfully completed scheduled and make-up sample days in that month. In exercising his discretion, the Administrator will consider whether the approach specified in 6(a)(i) might in the Administrator's judgment result in an unrepresentative value for the monthly mean concentration. This provision is to protect the integrity of the monthly and 3-month mean concentration values in situations in which, by intention or otherwise, extra sampling days are concentrated in a period during which ambient concentrations are particularly high or low. The alternate approach is to average all extra and make-up samples (in the given month) taken after each scheduled sampling day (''Day X'') and before the next scheduled sampling day (e.g., ''Day X+6'', in the case of one-in-six sampling) with the sample taken on Day X (assuming valid data was obtained on the scheduled sampling day), and then averaging these averages to calculate the monthly mean. This approach has the effect of giving approximately equal weight to periods during a month that have equal number of days, regardless of how many samples were actually obtained during the periods, thus mitigating the potential for the monthly mean to be distorted. The first day of scheduled sampling typically will not fall on the first day of the calendar month, and there may be make-up and/or extra samples (in that same calendar month) preceding the first scheduled day of the month. These samples will not be shifted into the previous month's mean concentration, but rather will stay associated with their actual calendar month as follows. Any extra and make-up samples taken in a month before the first scheduled sampling day of the month will be associated with and averaged with the last scheduled sampling day of that same month.

(b) Three-month parameter means are determined by averaging three consecutive monthly means of the same parameter using Equation 2 of this appendix.

Equation 2

$$\bar{X}_{m1,m2,m3;s} = \frac{1}{n_m}\sum_{i=1}^{n_m} \bar{X}_{m,y:z,s}$$

Where:

$\bar{X}_{m1,\ m2,\ m3;\ s}$ = the 3-month parameter mean for months m1, m2, and m3 for site s; and

n_m = the number of monthly means available to be averaged (typically 3, sometimes 1 or 2 if one or two months have no valid daily values); and

$X_{m,\ y:\ z,\ s}$ = The mean for month m of the year y (or z) for site s.

(c) Three-month site means are determined from available 3-month parameter means according to the hierarchy established in 2(a) of this appendix.

(d) The site-level Pb design value is the highest valid 3-month site-level mean over the most recent 38-month period (i.e., the most recent 3-year calendar period plus two previous months). Section 4(a) of this appendix explains when the identified design value is itself considered valid for purposes of determining that the NAAQS is met or violated at a site.

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 9. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 10. Section 51.117 is amended by revising paragraph (e)(1) to read as follows:

§ 51.117 Additional provisions for lead.

* * * * *

(e) * * *

(1) The point source inventory on which the summary of the baseline for lead emissions inventory is based must contain all sources that emit 0.5 or more tons of lead per year.

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PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 11. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart C—[Amended]

■ 12. Section 53.33 is revised to read as follows:

§ 53.33 Test Procedure for Methods for Lead (Pb).

(a) *General.* The reference method for Pb in TSP includes two parts, the reference method for high-volume sampling of TSP as specified in 40 CFR 50, Appendix B and the analysis method for Pb in TSP as specified in 40 CFR 50, Appendix G. Correspondingly, the reference method for Pb in PM_{10} includes the reference method for low-volume sampling of PM_{10} in 40 CFR 50, Appendix O and the analysis method of Pb in PM_{10} as specified in 40 CFR 50, Appendix Q. This section explains the procedures for demonstrating the equivalence of either a candidate method for Pb in TSP to the high-volume reference methods, or a candidate method for Pb in PM_{10} to the low-volume reference methods.

(1) Pb in TSP—A candidate method for Pb in TSP specifies reporting of Pb concentrations in terms of standard temperature and pressure. Comparisons of candidate methods to the reference method in 40 CFR 50, Appendix G must be made in a consistent manner with regard to temperature and pressure.

(2) Pb in PM_{10}—A candidate method for Pb in PM_{10} must specify reporting of Pb concentrations in terms of local conditions of temperature and pressure, which will be compared to similarly reported concentrations from the reference method in 40 CFR 50 Appendix Q.

(b) *Comparability.* Comparability is shown for Pb methods when the differences between:

(1) Measurements made by a candidate method, and

(2) Measurements made by the reference method on simultaneously collected Pb samples (or the same sample, if applicable), are less than or equal to the values specified in table C–3 of this subpart.

(c) *Test measurements.* Test measurements may be made at any number of test sites. Augmentation of pollutant concentrations is not permitted, hence an appropriate test site or sites must be selected to provide Pb concentrations in the specified range.

(d) *Collocated samplers.* The ambient air intake points of all the candidate and reference method collocated samplers shall be positioned at the same height above the ground level, and between 2 meters (1 meter for samplers with flow rates less than 200 liters per minute (L/min)) and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(e) *Sample collection.* Collect simultaneous 24-hour samples of Pb at the test site or sites with both the reference and candidate methods until at least 10 sample pairs have been obtained.

(1) A candidate method for Pb in TSP which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, Appendix B, but uses a different analytical procedure than specified in 40 CFR Appendix G, may be tested by analyzing pairs of filter strips taken from a single TSP reference sampler operated according to the procedures specified by that reference method.

(2) A candidate method for Pb in PM_{10} which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, Appendix O, but uses a different analytical procedure than specified in 40 CFR Appendix Q, requires the use of two PM_{10} reference samplers because a single 46.2-mm filter from a reference sampler may not be divided prior to analysis. It is possible to analyze a 46.2-mm filter first with the non-destructive X-ray Fluorescence (XRF) FRM and subsequently extract the filter for other analytical techniques. If the filter is subject to XRF with subsequent extraction for other analyses, then a single PM_{10} reference sampler may be used for sample collection.

(3) A candidate method for Pb in TSP or Pb in PM_{10} which employs a direct reading (e.g., continuous or semi-continuous sampling) method that uses the same sampling inlet and flow rate as the FRM and the same or different analytical procedure may be tested. The direct measurements are then aggregated to 24-hour equivalent concentrations for comparison with the FRM. For determining precision in section (k), two collocated direct reading devices must be used.

(f) *Audit samples.* Three audit samples must be obtained from the address given in § 53.4(a). For Pb in TSP collected by the high-volume sampling method, the audit samples are ¾ x 8-inch glass fiber strips containing known amounts of Pb in micrograms per strip (µg/strip) equivalent to the following nominal percentages of the National Ambient Air Quality Standard (NAAQS): 30%, 100%, and 250%. For Pb in PM_{10} collected by the low-volume sampling method, the audit samples are 46.2-mm polytetrafluorethylene (PTFE) filters containing known amounts of Pb in micrograms per filter (µg/filter) equivalent to the same percentages of the NAAQS: 30%, 100%, and 250%. The true amount of Pb (Tqi), in total µg/strip (for TSP) or total µg/filter (for PM_{10}), will be provided for each audit sample.

(g) *Filter analysis.*

(1) For both the reference method samples (e) and the audit samples (f), analyze each filter or filter extract three times in accordance with the reference method analytical procedure. This applies to both the Pb in TSP and Pb in PM_{10} methods. The analysis of replicates should not be performed sequentially, i.e., a single sample should not be analyzed three times in sequence. Calculate the indicated Pb concentrations for the reference method samples in micrograms per cubic meter (µg/m^3) for each analysis of each filter. Calculate the indicated total Pb amount for the audit samples in µg/strip for each analysis of each strip or µg/filter for each analysis of each audit filter. Label these test results as R_{1A}, R_{1B}, R_{1C}, R_{2A}, R_{2B}, etc., Q_{1A}, Q_{1B}, Q_{1C}, etc., where R denotes results from the reference method samples; Q denotes results from the audit samples; 1, 2, 3 indicate the filter number, and A, B, C indicate the first, second, and third analysis of each filter, respectively.

(2) For the candidate method samples, analyze each sample filter or filter extract three times and calculate, in accordance with the candidate method, the indicated Pb concentration in µg/m^3 for each analysis of each filter. The analysis of replicates should not be performed sequentially. Label these test results as C_{1A}, C_{1B}, C_{2C}, etc., where C denotes results from the candidate method. For candidate methods which provide a direct reading or measurement of Pb concentrations without a separable procedure, $C_{1A}=C_{1B}=C_{1C}$, $C_{2A}=C_{2B}=C_{2C}$, etc.

(h) *Average Pb concentration.* For the reference method, calculate the average Pb concentration for each filter by averaging the concentrations calculated from the three analyses as described in (g)(1) using equation 1 of this section:

Equation 1

$$R_{iave} = \frac{(R_{iA} + R_{iB} + R_{iC})}{3}$$

Where, i is the filter number.

(i) *Analytical Bias.*

(1) For the audit samples, calculate the average Pb concentration for each strip or filter analyzed by the reference method by averaging the concentrations calculated from the three analyses as described in (g)(1) using equation 2 of this section:

Equation 2

$$Q_{iave} = \frac{(Q_{iA} + Q_{iB} + Q_{iC})}{3}$$

Where, i is audit sample number.

(2) Calculate the percent difference (D_q) between the average Pb concentration for each audit sample and the true Pb concentration (T_q) using equation 3 of this section:

Equation 3

$$D_{qi} = \frac{Q_{iave} - T_{qi}}{T_{qi}} \times 100$$

(3) If any difference value (D_{qi}) exceeds ±5 percent, the bias of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source of the error(s) (e.g., calibration standard discrepancies, extraction problems, etc.) and the reference method and audit sample determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(j) *Acceptable filter pairs.* Disregard all filter pairs for which the Pb concentration, as determined in paragraph (h) of this section by the average of the three reference method determinations, falls outside the range of 30% to 250% of the Pb NAAQS level in µg/m^3 for Pb in both TSP and PM_{10}. All remaining filter pairs must be subjected to the tests for precision and comparability in paragraphs (k) and (l) of this section. At least five filter pairs

must be within the specified concentration range for the tests to be valid.

(k) *Test for precision.*

(1) Calculate the precision (P) of the analysis (in percent) for each filter and for each method, as the maximum minus the minimum divided by the average of the three concentration values, using equation 4 or equation 5 of this section:

Equation 4

$$P_{Ri} = \frac{R_{i\max} - R_{i\min}}{R_{iave}} \times 100$$

or

Equation 5

$$P_{Ci} = \frac{C_{i\max} - C_{i\min}}{C_{iave}} \times 100$$

Where, i indicates the filter number.

(2) If a direct reading candidate method is tested, the precision is determined from collocated devices using equation 5 above.

(3) If any reference method precision value (P_{Ri}) exceeds 15 percent, the precision of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source(s) of imprecision, and the reference method determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(4) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the candidate method fails the precision test.

(5) The candidate method passes this test if all precision values (*i.e.*, all P_{Ri}'s and all P_{Ci}'s) are less than 15 percent.

(l) *Test for comparability.*

(1) For each filter or analytical sample pair, calculate all nine possible percent differences (D) between the reference and candidate methods, using all nine possible combinations of the three determinations (A, B, and C) for each method using equation 6 of this section:

Equation 6

$$D_{in} = \frac{C_{ij} - R_{jk}}{R_{jk}} \times 100$$

Where, i is the filter number, and n numbers from 1 to 9 for the nine possible difference combinations for the three determinations for each method (j = A, B, C, candidate; k = A, B, C, reference).

(2) If none of the percent differences (D) exceeds ±20 percent, the candidate method passes the test for comparability.

(3) If one or more of the percent differences (D) exceed ±20 percent, the candidate method fails the test for comparability.

(4) The candidate method must pass both the precision test (paragraph (k) of this section) and the comparability test (paragraph (l) of this section) to qualify for designation as an equivalent method.

(m) *Method Detection Limit (MDL).* Calculate the estimated MDL using the guidance provided in 40 CFR, Part 136 Appendix B. It is essential that all sample processing steps of the analytical method be included in the determination of the method detection limit. Take a minimum of seven blank filters from each lot to be used and calculate the detection limit by processing each through the entire candidate analytical method. Make all computations according to the defined method with the final results in μg/m³. The MDL of the candidate method must be equal to, or less than 5% of the level of the Pb NAAQS.

■ 13. Table C–3 to Subpart C of Part 53 is revised to read as follows:

TABLE C–3 TO SUBPART C OF PART 53—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM_{10} METHODS

Concentration range equivalent to percentage of NAAQS in μg/m³.	30% to 250%
Minimum number of 24-hr measurements.	5
Maximum reference method analytical bias, D_q.	±5%
Maximum precision, P_R or P_C ..	≤15%
Maximum difference (D)	±20%
Estimated Method Detection Limit (MDL), μg/m³.	5% of NAAQS level.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 14. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart B—[Amended]

■ 15. Section 58.10, is amended by added paragraph subsections (a)(4) and adding paragraph (b)(9) to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

* * * * *

(a) * * *

(4) A plan for establishing Pb monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the EPA Regional Administrator no later than July 1, 2009 as part of the annual network plan required in paragraph (a)(1) of this section. The plan shall provide for the required source-oriented Pb monitoring sites to be operational by January 1, 2010, and for all required non-source-oriented Pb monitoring sites to be operational by January 1, 2011. Specific site locations for the sites to be operational by January 1, 2011 are not required as part of the July 1, 2009 annual network plan, but shall be included in the annual network plan due to be submitted to the EPA Regional Administrator on July 1, 2010.

* * * * *

(b) * * *

(9) The designation of any Pb monitors as either source-oriented or non-source-oriented according to Appendix D to 40 CFR part 58.

(10) Any source-oriented monitors for which a waiver has been requested or granted by the EPA Regional Administrator as allowed for under paragraph 4.5(a)(ii) of Appendix D to 40 CFR part 58.

(11) Any source-oriented or non-source-oriented site for which a waiver has been requested or granted by the EPA Regional Administrator for the use of Pb-PM_{10} monitoring in lieu of Pb-TSP monitoring as allowed for under paragraph 2.10 of Appendix C to 40 CFR part 58.

* * * * *

■ 16. Section 58.13 is amended by revising paragraph (b) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(b) Not withstanding specific dates included in this part, beginning January 1, 2008, when existing networks are not in conformance with the minimum number of required monitors specified in this part, additional required monitors must be identified in the next applicable annual monitoring network plan, with monitoring operation beginning by January 1 of the following year. To allow sufficient time to prepare and comment on Annual Monitoring Network Plans, only monitoring requirements effective 120 days prior to the required submission date of the plan (i.e., 120 days prior to July 1 of each year) shall be included in that year's annual monitoring network plan.

■ 17. Section 58.16 is amended by revising paragraph (a) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2;

NO; NO_Y; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$ FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10-2.5}$ mass concentration; chemically speciated $PM_{10-2.5}$ mass concentration data; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (*http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm*). The State, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

Subpart D—[Amended]

■ 18. Section 58.20 is amended by revising paragraph (e) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(e) If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, SO_2, NO_2, or 24-hour PM_{10} NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

* * * * *

■ 19. Appendix A to Part 58 is amended to read as follows:

■ a. Revising paragraph 1,
■ b. Adding paragraph 2.3.1.4,
■ c. Revising paragraph 3.3.4,
■ d. Revising paragraph 4c,
■ e. Revising paragraph 4.4,
■ f. Removing paragraph 4.5 and
■ g. Revising Table A–2.

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

1. *General Information.*

This appendix specifies the minimum quality system requirements applicable to SLAMS air monitoring data and PSD data for the pollutants SO_2, NO_2, O_3, CO, Pb, $PM_{2.5}$, PM_{10} and $PM_{10-2.5}$ submitted to EPA. This appendix also applies to all SPM stations using FRM, FEM, or ARM methods which also meet the requirements of Appendix E of this part. Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the ''Quality Assurance Handbook for Air Pollution Measurement Systems'', volume II, part 1 (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

* * * * *

2.3.1.4 *Measurement Uncertainty for Pb Methods.* The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient variation (CV) of 20 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

* * * * *

3.3.4 *Pb Methods.*

3.3.4.1 *Flow Rates.* For the Pb Reference Methods (40 CFR Part 50, appendix G and appendix Q) and associated FEMs, the flow rates of the Pb samplers shall be verified and audited using the same procedures described in sections 3.3.2 and 3.3.3 of this appendix.

3.3.4.2 *Pb Analysis Audits.* Each calendar quarter or sampling quarter (PSD), audit the Pb Reference Method analytical procedure using filters containing a known quantity of Pb. These audit filters are prepared by depositing a Pb solution on unexposed filters and allowing them to dry thoroughly. The audit samples must be prepared using batches of reagents different from those used to calibrate the Pb analytical equipment being audited. Prepare audit samples in the following concentration ranges:

Range	Equivalent ambient Pb concentration, μg/m³
1	30–100% of Pb NAAQS.
2	200–300% of Pb NAAQS.

(a) Audit samples must be extracted using the same extraction procedure used for exposed filters.

(b) Analyze three audit samples in each of the two ranges each quarter samples are analyzed. The audit sample analyses shall be distributed as much as possible over the entire calendar quarter.

(c) Report the audit concentrations (in μg Pb/filter or strip) and the corresponding measured concentrations (in μg Pb/filter or strip) using AQS unit code 077. The percent differences between the concentrations are used to calculate analytical accuracy as described in section 4.1.3 of this appendix.

(d) The audits of an equivalent Pb method are conducted and assessed in the same manner as for the reference method. The flow auditing device and Pb analysis audit samples must be compatible with the specific requirements of the equivalent method.

3.3.4.3 *Collocated Sampling.* The collocated sampling requirements for Pb-TSP and Pb-PM_{10} shall be determined using the same procedures described in sections 3.3.1 of this appendix with the exception that the first collocated Pb site selected must be the site measuring the highest Pb concentrations in the network. If the site is impractical, alternative sites, approved by the EPA Regional Administrator, may be selected. If additional collocated sites are necessary, collocated sites may be chosen that reflect average ambient air Pb concentrations in the network.

3.3.4.4 *Pb Performance Evaluation Program (PEP) Procedures.* Each year, one performance evaluation audit, as described in section 3.2.7 of this appendix, must be performed at one Pb site in each primary quality assurance organization that has less than or equal to 5 sites and two audits at primary quality assurance organizations with greater than 5 sites. In addition, each year, four collocated samples from primary quality assurance organizations with less than or equal to 5 sites and six collocated samples at primary quality assurance organizations with greater than 5 sites must be sent to an independent laboratory, the same laboratory as the performance evaluation audit, for analysis.

* * * * *

4. *Calculations for Data Quality Assessment.*

* * * * *

(c) At low concentrations, agreement between the measurements of collocated samplers, expressed as relative percent difference or percent difference, may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision and bias calculations only when both measurements are equal to or above the following limits:

(1) TSP: 20 μg/m³.
(2) Pb: 0.02 μg/m³.
(3) PM_{10} (Hi-Vol): 15 μg/m³.
(4) PM_{10} (Lo-Vol): 3 μg/m³.
(5) $PM_{10-2.5}$ and $PM_{2.5}$: 3 μg/m³.

* * * * *

4.4 *Statistics for the Assessment of Pb.*

4.4.1 *Precision Estimate.* Follow the same procedures as described for PM_{10} in section 4.2.1 of this appendix using the data from the collocated instruments. The data pair would only be considered valid if both concentrations are greater than the minimum values specified in section 4(c) of this appendix.

4.4.2 *Bias Estimate.* For the Pb analysis audits described in section 3.3.4.2 and the Pb Performance Evaluation Program described in section 3.3.4.4, follow the same procedure as described in section 4.1.3 for the bias estimate.

4.4.3 *Flow rate calculations.* For the one point flow rate verifications, follow the same procedures as described for PM_{10} in section 4.2.2; for the flow rate audits, follow the

same procedures as described in section 4.2.3.

* * * * *

TABLE A–2 OF APPENDIX A TO PART 58—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Automated Methods				
1-Point QC for SO_2, NO_2, O_3, CO.	Response check at concentration 0.01–0.1 ppm SO_2, NO_2, O_3, and 1–10 ppm CO.	Each analyzer	Once per 2 weeks	Audit concentration [1] and measured concentration [2].
Annual performance evaluation for SO_2, NO_2, O_3, CO.	See section 3.2.2 of this appendix.	Each analyzer	Once per year	Audit concentration [1] and measured concentration [2] for each level.
Flow rate verification PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Collocated sampling $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	15%	Every 12 days	Primary sampler concentration and duplicate sampler concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated sampling PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Collocated samplers	15%	Every 12 days PSD—every 6 days.	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM_{10} (low Vol), $PM_{10-2.5}$, $PM_{2.5}$, Pb-PM_{10}.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Flow rate verification PM_{10} (High-Vol), TSP, Pb-TSP.	Check of sampler flow rate	Each sampler	Once every quarter	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Check of sampler flow rate using independent standard.	Each sampler, all locations	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Pb audit strips Pb-TSP, Pb-PM_{10}.	Check of analytical system with Pb audit strips.	Analytical	Each quarter	Actual concentration and audit concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Performance evaluation program Pb-TSP, Pb-PM_{10}.	Collocated samplers	1. 1 valid audit and 4 collocated samples for primary QA orgs, with >5 sites. 2. 2 valid audits and 6 collocated samples for primary QA orgs, with >5 sites.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable, for open path analyzers.

■ 20. Appendix C to Part 58 is amended by adding paragraph 2.10 to read as follows:

* * * * *

2.10 *Use of Pb-PM_{10} at SLAMS Sites.*

2.10.1 The EPA Regional Administrator may approve the use of a Pb-PM_{10} FRM or Pb-PM_{10} FEM sampler in lieu of a Pb-TSP sampler as part of the network plan required under part 58.10(a)(4) in the following cases.

2.10.1.1 Pb-PM_{10} samplers can be approved for use at the non-source-oriented sites required under paragraph 4.5(b) of

Appendix D to part 58 if there is no existing monitoring data indicating that the maximum arithmetic 3-month mean Pb concentration (either Pb-TSP or Pb-PM_{10}) at the site was equal to or greater than 0.10 micrograms per cubic meter during the previous 3 years.

2.10.1.2 Pb-PM_{10} samplers can be approved for use at source-oriented sites required under paragraph 4.5(a) if the monitoring agency can demonstrate (through modeling or historic monitoring data from the last 3 years) that Pb concentrations (either Pb-TSP or Pb-PM_{10}) will not equal or exceed 0.10 micrograms per cubic meter on an arithmetic 3-month mean and the source is expected to emit a substantial majority of its Pb in the fraction of PM with an aerodynamic diameter of less than or equal to 10 micrometers.

2.10.2 The approval of a Pb-PM_{10} sampler in lieu of a Pb-TSP sampler as allowed for in paragraph 2.10.1 above will be revoked if measured Pb-PM_{10} concentrations equal or exceed 0.10 micrograms per cubic meter on an arithmetic 3-month mean. Monitoring agencies will have up to 6 months from the end of the 3-month period in which the arithmetic 3-month Pb-PM_{10} mean concentration equaled or exceeded 0.10 micrograms per cubic meter to install and begin operation of a Pb-TSP sampler at the site.

■ 22. Appendix D to Part 58 is amended by revising paragraph 4.5 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.5 *Lead (Pb) Design Criteria.* (a) State and, where appropriate, local agencies are required to conduct ambient air Pb monitoring taking into account Pb sources which are expected to or have been shown to contribute to a maximum Pb concentration in ambient air in excess of the NAAQS, the potential for population exposure, and logistics. At a minimum, there must be one source-oriented SLAMS site located to measure the maximum Pb concentration in ambient air resulting from each Pb source which emits 1.0 or more tons per year based on either the most recent National Emission Inventory (*http://www.epa.gov/ttn/chief/eiinformation.html*) or other scientifically justifiable methods and data (such as improved emissions factors or site-specific data) taking into account logistics and the potential for population exposure.

(i) One monitor may be used to meet the requirement in paragraph 4.5(a) for all sources involved when the location of the maximum Pb concentration due to one Pb source is expected to also be impacted by Pb emissions from a nearby source (or multiple sources). This monitor must be sited, taking into account logistics and the potential for population exposure, where the Pb concentration from all sources combined is expected to be at its maximum.

(ii) The Regional Administrator may waive the requirement in paragraph 4.5(a) for monitoring near Pb sources if the State or, where appropriate, local agency can demonstrate the Pb source will not contribute to a maximum Pb concentration in ambient air in excess of 50% of the NAAQS (based on historical monitoring data, modeling, or other means). The waiver must be renewed once every 5 years as part of the network assessment required under 58.10(d).

(b) State and, where appropriate, local agencies are required to conduct Pb monitoring in each CBSA with a population equal to or greater than 500,000 people as determined by the latest available census figures. At a minimum, there must be one non-source-oriented SLAMS site located to measure neighborhood scale Pb concentrations in urban areas impacted by re-entrained dust from roadways, closed industrial sources which previously were significant sources of Pb, hazardous waste sites, construction and demolition projects, or other fugitive dust sources of Pb.

(c) The EPA Regional Administrator may require additional monitoring beyond the minimum monitoring requirements contained in 4.5(a) and 4.5(b) where the likelihood of Pb air quality violations is significant or where the emissions density, topography, or population locations are complex and varied.

(d) The most important spatial scales for source-oriented sites to effectively characterize the emissions from point sources are microscale and middle scale. The most important spatial scale for non-source-oriented sites to characterize typical lead concentrations in urban areas is the neighborhood scale. Monitor siting should be conducted in accordance with 4.5(a)(i) with respect to source-oriented sites.

(1) Microscale—This scale would typify areas in close proximity to lead point sources. Emissions from point sources such as primary and secondary lead smelters, and primary copper smelters may under fumigation conditions likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Pb monitors in areas where the public has access, and particularly children have access, are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations.

(2) Middle scale—This scale generally represents Pb air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may for example, include schools and playgrounds in center city areas which are close to major Pb point sources. Pb monitors in such areas are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations (reference 3 of this appendix). Emissions from point sources frequently impact on areas at which single sites may be located to measure concentrations representing middle spatial scales.

(3) Neighborhood scale—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Sites of this scale would provide monitoring data in areas representing conditions where children live and play. Monitoring in such areas is important since this segment of the population is more susceptible to the effects of Pb. Where a neighborhood site is located away from immediate Pb sources, the site may be very useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(d) Technical guidance is found in references 4 and 5 of this appendix. These documents provide additional guidance on locating sites to meet specific urban area monitoring objectives and should be used in locating new sites or evaluating the adequacy of existing sites.

* * * * *

[FR Doc. E8–25654 Filed 11–10–08; 8:45 am]

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November 12, 2008

Part III

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1, Parts 2, 3, et al.
Federal Acquisition Regulation; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2008–0003, Sequence 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–28; Introduction

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rule.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rule agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council in this Federal Acquisition Circular (FAC) 2005–28. A companion document, the Small Entity Compliance Guide (SECG), follows this FAC. The FAC, including the SECG, is available via the Internet at *http://www.regulations.gov.*

DATES: For effective date, *see* the document following this notice.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below in relation to the FAR case. Please cite FAC 2005–28, FAR Case 2007–006. For information pertaining to status or publication schedules, contact the FAR Secretariat at (202) 501–4755.

Rule listed in FAC 2005–28.

Item	Subject	FAR case	Analyst
I	Contractor Business Ethics Compliance Program and Disclosure Requirements	2007–006	Woodson.

SUPPLEMENTARY INFORMATION: A summary of the FAR rule follows. For the actual revisions and/or amendments to this FAR case, refer to FAR Case 2007–006.

FAC 2005–28 amends the FAR as specified below: Item I—Contractor Business Ethics Compliance Program and Disclosure Requirements (FAR Case 2007–006).

This final rule amends the Federal Acquisition Regulation to amplify the requirements for a contractor code of business ethics and conduct, an internal control system, and disclosure to the Government of certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. The rule provides for the suspension or debarment of a contractor for knowing failure by a principal to timely disclose, in writing, to the agency Office of the Inspector General, with a copy to the contracting officer, certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. The final rule implements ''The Close the Contractor Fraud Loophole Act,'' Public Law 110–252, Title VI, Chapter 1. The statute defines a covered contract to mean ''any contract in an amount greater than $5,000,000 and more than 120 days in duration.'' The final rule also provides that the contractor's Internal Control System shall be established within 90 days after contract award, unless the Contracting Officer establishes a longer time period (*See* FAR 52.203–13(c)). The internal control system is not required for small businesses or commercial item contracts.

Dated: November 5, 2008.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E8–26810 Filed 11–10–08; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 3, 9, 42 and 52

[FAC 2005–28; FAR Case 2007–006; Item I; Docket 2007–001; Sequence 11]

RIN 9000–AK80

Federal Acquisition Regulation; FAR Case 2007–006, Contractor Business Ethics Compliance Program and Disclosure Requirements

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) have agreed on a final rule amending the Federal Acquisition Regulation (FAR) to amplify the requirements for a contractor code of business ethics and conduct, an internal control system, and disclosure to the Government of certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. This final rule implements Pub. L. 110–252, Title VI, Chapter 1.

DATES: *Effective Date:* December 12, 2008.

Applicability: The Contractor's Internal Control System shall be established within 90 days after contract award, unless the Contracting Officer establishes a longer time period (*See* FAR 52.203–13(c)). The Internal Control System is not required for small businesses or for commercial item contracts.

FOR FURTHER INFORMATION CONTACT: Mr. Ernest Woodson, Procurement Analyst, at (202) 501–3775 for clarification of content. For information pertaining to status or publication schedules, contact the FAR Secretariat at (202) 501–4755. Please cite FAC 2005–28, FAR case 2007–006.

SUPPLEMENTARY INFORMATION:

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C. Regulatory Flexibility Act
D. Paperwork Reduction Act

A. Background

This case is in response to a request to the Office of Federal Procurement Policy from the Department of Justice, dated May 23, 2007, and the Close the Contractor Fraud Loophole Act, Public Law 110–252, Title VI, Chapter 1. This final rule amends the Federal Acquisition Regulation to require Government contractors to—

• Establish and maintain specific internal controls to detect and prevent improper conduct in connection with the award or performance of *any* Government contract or subcontract; and

• Timely disclose to the agency Office of the Inspector General, with a copy to the contracting officer, whenever, in connection with the award, performance, or closeout of a Government contract performed by the contractor or a subcontract awarded thereunder, the contractor has credible evidence of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code; or a violation of the civil False Claims Act (31 U.S.C. 3729–3733).

• The rule also provides as cause for suspension or debarment, knowing failure by a principal, until 3 years after final payment on any Government contract awarded to the contractor, to timely disclose to the Government, in connection with the award, performance, or closeout of the contract or a subcontract thereunder, credible evidence of—

A. Violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code;

B. Violation of the civil False Claims Act; or

C. Significant overpayment(s) on the contract, other than overpayments resulting from contract financing payments as defined in FAR 32.001, Definitions.

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 72 FR 64019, November 14, 2007, entitled ''Contractor Compliance Program and Integrity Reporting.'' The public comment period closed on January 14, 2008. (This was a follow-on case to the final rule under FAC 2005–22, FAR case 2006–007 that was published in the **Federal Register** at 72 FR 65868, November 23, 2007, effective December 24, 2007.) A second proposed rule was published in the **Federal Register** at 73 FR 28407, May 16, 2008, entitled ''Contractor Compliance Program and Integrity Reporting.'' The public comment period on the second proposed rule closed on July 15, 2008.

On June 30, 2008, the Close the Contractor Fraud Loophole Act (Pub. L. 110–252, Title VI, Chapter 1) was enacted as part of the Supplemental Appropriations Act, 2008. This Act requires revision to the FAR within 180 days of enactment, pursuant to 2007–006, ''or any follow-on FAR case to include provisions that require timely notification by Federal contractors of violations of Federal criminal law or overpayments in connection with the award or performance of covered contracts or subcontracts, including those performed outside the United States and those for commercial items.'' The statute also defines a covered contract to mean ''any contract in an amount greater than $5,000,000 and more than 120 days in duration.''

First proposed rule. The first proposed rule, published in the **Federal Register** on November 14, 2007, proposed the following:

1. *New causes for suspension/debarment.* A contractor may be suspended and/or debarred for knowing failure to timely disclose—

• An overpayment on a Government contract; or

• A violation of Federal criminal law in connection with the award or performance of any Government contract or subcontract.

2. *Changes to the requirement for a code of business ethics and conduct (52.203–XX).*

• Amplify the requirement to promote compliance with the code of business ethics.

• Require timely disclosure to the agency Office of the Inspector General (OIG), with a copy to the contracting officer, whenever the contractor has reasonable grounds to suspect a violation of criminal law in connection with the award or performance of the contract or any subcontract thereunder.

3. *Mandatory requirements for internal control system based on U.S. Sentencing Guidelines (USSG).*

• Provide more detail with regard to the ongoing business ethics awareness and compliance program (see 52.203–XX paragraph(c)(1)).

• Make all the stated elements of the internal control system mandatory, rather than examples (see 52.203–XX (c)(2)(ii)).

A. Add a new paragraph requiring assignment of responsibility within the organization for the ethics awareness and compliance program and internal control system.

B. Require reasonable efforts not to include as principals individuals who have engaged in illegal conduct or conduct otherwise in conflict with the contractor's code of business ethics and conduct.

C. Provide additional detail with regard to the requirement for periodic reviews.

D. Require that the internal reporting mechanism or hotline must allow for anonymity or confidentiality.

E. Provide that disciplinary action will be taken not only for improper conduct, but also for failing to take reasonable steps to prevent or detect improper conduct.

F. Require timely disclosure, in writing, to the agency OIG, with a copy to the contracting officer, whenever the contractor has reasonable grounds to believe that a violation of Federal criminal law has been committed in connection with the award or performance of any Government contract performed by the contractor or the award or performance of a subcontract thereunder.

G. Require full cooperation with any Government agencies responsible for audit, investigation, or corrective actions.

Second proposed rule. The second proposed rule, published in the **Federal Register** on May 16, 2008, proposed the following:

1. Require inclusion of the clause at FAR 52.203–13 in contracts and subcontracts that will be performed outside the United States.

2. Require inclusion of the clause at FAR 52.203–13 in contracts (and subcontracts) for all acquisitions of a commercial item. However, similar to small businesses, a formal business ethics awareness and compliance program and internal control system are not required in contracts and subcontracts for the acquisition of commercial items.

3. Add a new cause for suspension and/or debarment, *i.e.*, knowing failure to timely disclose the violation of the civil False Claims Act (civil FCA) in connection with the award or performance of any Government contract or subcontract.

The first two of these three proposed changes are now required by statute (Pub. L. 110–252, Title VI, Chapter 1). (As pointed out by one of the respondents, there was an error in the amendatory language in the **Federal Register**. At FAR 3.1004, the introductory text should have been deleted, rather than showing 5 asterisks, indicating that the introductory text is still present. However, the preamble made our intent very clear and this will be clarified in the final rule).

Rule on Contract Debts. DoD, GSA, and NASA published a proposed rule, FAR case 2005–018, in the **Federal**

Register at 71 FR 62230, October 24, 2006, regarding contract debts. The final rule was published in the **Federal Register** at 73 FR 53997, September 17, 2008, as part of Federal Acquisition Circular 2005–27. The intent of this rule is to evaluate existing controls and procedures for ensuring that contract debts are identified and recovered in a timely manner, properly accounted for in each agency's books and records, and properly coordinated with the appropriate Government officials.

One of the following payment clauses should be included in each Government solicitation and contract:

—52.212–4, Contract Terms and Conditions—Commercial Items, basic clause and Alternate I.
—52.232–25, Prompt Payment.
—52.232–26, Prompt Payment for Fixed-Price Architect-Engineer Contracts.
—52.232–27, Prompt Payment for Construction Contracts.

These Payment clauses for years have contained the requirement to immediately notify the contracting officer if the contractor becomes aware of any overpayment on a contract financing or invoice payment. Compliance with this requirement fulfills the statutory requirement of Pub. L. 110–252 for timely notification of overpayments.

In addition, under the Contract Debts rule, these Payment clauses were modified to require that if the contractor becomes aware of a duplicate contract financing or invoice payment or if the contractor becomes aware that the Government has otherwise overpaid on a contract financing or invoice payment, the contractor shall—

• Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment; and

• Provide a copy of the remittance and supporting documentation to the contracting officer.

Because issues of overpayment were addressed in FAR case 2005–018, the Councils did not include additional coverage on contract debt in the subject FAR Case, except for adding—

• Knowing failure to timely disclose significant overpayment as a cause for debarment/suspension as stated at Subpart 9.4 Debarment, Suspension, and Ineligibility; and

• A cross reference at 3.1003(a)(3) to this new cause of suspension/debarment at Subpart 9.4.

B. Discussion and Analysis

The FAR Secretariat received 43 responses to the first proposed rule. The FAR Secretariat received comments on the second proposed rule from 25 respondents of which 15 respondents had also submitted comments on the first proposed rule and 10 respondents were submitting comments for the first time. Overall, 18 of the 53 respondents were from Government agencies, including many responses from agency Offices of the Inspector General (OIG).

In the second proposed rule the Councils specifically requested comments on three issues:

• Elimination of the exemption from inclusion of the clause FAR 52.203–13 for contracts and subcontracts that will be performed entirely outside the United States.

• Elimination of the exemption from inclusion of the clause FAR 52.203–13 for contracts (and subcontracts) for all acquisitions of a commercial item under FAR Part 12.

• Requirement for mandatory disclosure of violations of the civil FCA (31 U.S.C. 3729–3733) (in the clause, in the internal control system required by the clause, and as a cause for suspension or debarment).

Comments on the second proposed rule that do not relate to these three issues, unless presenting a new and pertinent perspective, have not been separately addressed in this preamble.

1. Interrelationship of Previous Final Rule, First Proposed Rule, Second Proposed Rule, and New Statute

a. Previous Final Rule, FAR Case 2006–007

The first proposed rule under FAR case 2007–006 (''first proposed rule''), proposed increases to the requirements introduced by final rule, FAR case 2006–007 (''previous final rule''), in the ways enumerated in the Background section above. Thirteen respondents remarked on the relationship to the previous final rule, some suggesting changes to the previous final rule as well as the first proposed rule.

i. Like the previous final rule under 2006–007.

• No further change needed. One respondent expressed the belief that the previous final rule is adequate to protect the Government's interest. Several other respondents supported the previous final rule's voluntary disclosure. One respondent questioned the need for the first proposed rule in light of the recent implementation of ''more expansive contractor compliance standards in the FAR.''

• The first and second proposed rules enhance the previous rule. One Government agency explicitly supported the major provisions of both rules as sound business practices, highlighting their contribution to cost control as well as mission safety.

Response: No response necessary.

ii. Ethics code. With regard to the requirement for a code of conduct, one respondent considered that just having a code is meaningless. Several other respondents also objected to the requirement for a code of business ethics and conduct in the previous final rule under FAR case 2006–007, stating that existing contractor ethics standards work well and that these contractual requirements are redundant, add costs and other burdens, and are likely to generate additional uncertainties.

Several respondents objected to the outdated method of communicating the code, requiring a copy to each employee engaged in the contract. One respondent recommended that it may be more effective to refer employees to Web sites or provide tutorials in person, on-line, or through other means. This suggestion could minimize burdens through the use of information technology, as requested in the preamble to the proposed rule for this case.

Another respondent also objected that many institutions have more than a single code of conduct, each addressing different aspects of conduct that together cover all aspects of conduct that the FAR rule requires.

Response: The Councils do not agree that a code of conduct is meaningless. It can serve several related purposes. For a firm's business partners, including the Government, it provides a basis for evaluating the firm's responsibility, including special standards of responsibility when appropriate. It also provides a basis for internal policy development, for example human resources policies. And when something goes wrong, the code is meaningful for enforcement and for understanding and perhaps incorporating lessons learned.

While requiring establishment of a code will add costs and require effort on the part of entities that do not have them already, the Councils agree with several respondents that those resources are reasonable and justified to mitigate other and larger risks to the success and efficiency of Government projects. Because many entities already have made the investment, the rule will level the playing field in competitive environments.

The Councils agree that flexibility in the method of communicating the code to employees is appropriate, and the rule has been changed to require that it be made available to each employee engaged in performance of the contract. The Councils note that the rule does not preclude having multiple codes of

conduct applicable to different segments of contractors' business lines.

iii. Training.

• Training requirement is too burdensome. One respondent was concerned that the requirements for training could take substantial time away from performing on their contracts to train staff on an unknown scope of Federal criminal law. The Government would incur costs from this activity through delays in the fulfillment of contracts and increased contractor expenses that will be passed along to customers.

Response: The Councils recognize that contract costs are reflected in prices, but do not consider schedules to be impacted by this requirement. By identifying the scope of violations of the Federal criminal law as those involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code, the Councils believe that the training requirements have been more clearly defined and the contractor's training requirement has been reduced.

• Require training on civil FCA. Several respondents proposed that Government contractors be required to educate their employees about the protections available under the civil FCA. The Department of Justice, Criminal Division (DoJ) suggested that contractors should also be required to include in their ''business ethics awareness'' obligation, reflected in the proposed rule at FAR 52.203–13(c)(2)(ii)(F), training on the civil FCA.

Response: The Councils do not agree that it is necessary under this case to dictate to contractors what they need to cover in business ethics training. If we highlight education on the civil FCA, or other specific areas, the contractors may place undue emphasis only on those areas mentioned in the regulations. The business ethics training courses may cover appropriate education on the civil FCA, as well as many other areas such as conflict of interest and procurement integrity and other areas determined to be appropriate by the contractor, considering the relevant risks and controls.

iv. Hotline posters. One respondent commented that the physical display of multiple hotline posters in common work areas is impractical and wasteful. Another respondent also objects to using hotline posters on the walls of the institution as being the most effective way of communication at every institution.

Response: The issue of multiple hotline posters was resolved under the final rule 2006–007. The requirement for hotline posters is outside the scope of this case.

b. Relationship of Second Proposed Rule to First Proposed Rule

One respondent questioned whether certain requirements of the first proposed rule that did not appear in the second proposed rule had been deleted.

Response: The preamble of the second proposed rule specified that it included only the sections of the rule affected by the three changes; it was only addressing three issues, not providing a completely revised proposed rule. Therefore, the fact that language in the first proposed rule that would not be affected by the 3 issues of concern was not repeated in the second proposed rule does not imply that that language was being deleted.

c. Relationship of Second Proposed Rule to New Statute

One respondent recommends that any disclosure requirement be limited to violations of the types specified in the ''Closing the Contractor Fraud Loophole Act (Pub. L. 110–252, Title VI, Chapter 1)'' (*i.e.*, exclude violations of the civil FCA). This respondent also states that the statute does not require the disclosure to the OIG and the penalties of debarment/suspension are not required by the new statute, so should be eliminated.

Another respondent also makes the point that since the new law does not address disclosure of violations of the civil FCA, that requirement should not be included in the final rule under this case.

One respondent notes particularly that the new law does not require the ''reasonable grounds to believe'' standard, reporting to the Inspector General, or failure to report as an independent basis for suspension or debarment.

Response: This rule was initiated as a matter of policy. Although the new statute reinforces and provides a statutory basis for some aspects of the rule, the fact that any part of the rule is not required by statute does not alter the rationale that provided the underpinning for those aspects of the rule. Each aspect of the rule not required by statute must be considered on its own merits.

2. Mandatory Standards for Internal Control System

a. Minimum Requirements for the Internal Control System

One respondent considered that the previously recommended, now mandatory, internal control practices will be inadequate if they are considered to be maximum as well as minimum requirements. Another respondent considered the establishment of an internal control system that satisfies a laundry list of mandates will be overly burdensome. Another respondent would prefer that contractors be left free to choose to implement the USSG ''in the prudent exercise of their business discretion,'' rather than being required to do so. Likewise, another respondent stated that contractors may want to consider the USSG in designing compliance programs but, absent a statute or Executive order, they should not be made mandatory in the regulations.

Response: The rule does reflect minimum expectations. Competing firms are free to establish the highest ethical standards they consider to be appropriate to the business at hand. This case establishes a framework for institutional ethics management and disclosure and does not prescribe specific ethical requirements.

b. Relation of Rule to the USSG

i. Rule is consistent with the USSG. An agency OIG stated that the proposed rule should benefit Federal contractors. It provides guidance for contractors consistent with U.S. Sentencing Commission guidance on effective compliance and ethics programs for organizations. Compliance with the rule should assist contractors subject to the Sarbanes-Oxley Act of 2002 in fulfilling their responsibilities under the Act.

Response: None needed.

ii. USSG should be incorporated by reference. Several respondents commented that rather than using the ad hoc form of the USSG standards for compliance and ethics program, the actual USSG standards should simply be incorporated by reference. Conformity with the USSG will prevent contractors unknowingly failing to comply with all the USSG although complying with the FAR. Formal adoption of the USSG will create uniform criteria. A respondent recommended that all the descriptive paragraphs in (ii) be deleted, instead inserting: ''The Contractor's internal control system shall provide for a compliance and ethics program that meets the standards of the Federal Organizational Sentencing Guidelines, as amended from time to time, United States Sentencing Commission Guidelines Manual: Sentencing of Organizations, section 8B2.1.

Response: These respondents would use the USSG Guidelines, in place of the FAR spelling out the required elements of internal control systems. However,

the Councils prefer to spell out the elements. This lets the contractors know what is expected. The USSG are the source of the FAR text, but the FAR text is intentionally not adopting them verbatim. The procurement regulations are not the USSG; the contractor setting up an internal control system is in a different situation than a company accused of a crime. Some elements of the USSG are not appropriate for a procurement regulation. However, by making the minimum requirements generally consistent with the USSG, the Councils believe that a contractor should be in a better position if accused of a crime.

iii. Essential parts of the USSG are missing. One respondent commented that essential parts of the USSG are missing. One example is the reference to the use of an incentive system in compliance programs that encourages and rewards companies for implementing effective programs, following the model of the Organizational Sentencing Guidelines. The respondent recommends modifying 52.203–13(c)(1)(ii)(E) by inserting after ''detect improper conduct'' the words ''and appropriate incentives to perform in accordance with the compliance and ethics program''.

Another example the respondent uses is the standard for effectively responding to violations, and taking steps to prevent recurrence. Without these, a company's program would not be considered effective under the USSG.

Response: The Councils note that the respondent must have intended to cite FAR 52.203–13(c)(2)(ii)(E). The Councils do not want to require incentives for employees within contractors' internal control systems. This is within companies' discretion. The mitigating factors for debarment (9.406–1(a)) already include consideration of remedial action (*e.g.*, (6), (7), and (8)) taken by the contractor.

The FAR does cover responding to violations, and preventing recurrence, in FAR 52.203–13(c)(2)(i), and throughout (c)(2)(ii).

c. Principals

Several respondents asked for interpretation of the clause paragraph (c)(2)(ii)(B) requirement that the internal control system provide for reasonable efforts not to include within the organization principals whom due diligence would have exposed as having engaged in conduct that is illegal or otherwise in conflict with the Contractor's code of business ethics and conduct.''

- Is the ''organization'' the entire contractor, instead of the organization responsible for the code?
- Is the code retroactive to catch criminal behavior in the past?
- Is it only Federal crimes, or state and local as well?
- What about non-criminal behavior that did not violate the Contractor's code at the time?
- What kind of due diligence is necessary—a simple pre-employment questionnaire, or instead a costly background check with interviews of friends and neighbors?

Response:

- The Councils have revised the draft final rule (paragraphs (c)(2)(ii)(A), (B), and (C) of the clause 52.203–13) to eliminate use of the term ''organization''. This term was a carryover from the USSG. This rule is addressed to the contractor—the entity that signed the contract, and subcontractors thereunder.
- The code of conduct is not itself retroactive. However, it is necessary to distinguish conduct of an employee during his/her employment, from past conduct uncovered during a background check of a prospective hire. That past conduct need not be disclosed to the Government, but should be part of the decision whether to hire the individual.
- Past criminal behavior of any type, even criminal behavior unrelated to contracting, calls into question whether the individual at the present time has integrity and is a proper role model for company staff. This is not a mandate to fire the individual, but to determine whether the individual is currently trustworthy to serve as a principal of the company.
- Behavior that was not criminal and did not violate a business's code as it existed at the time, is not the subject of this rule. In response to this comment, the Councils have revised paragraph (c)(2)(ii)(B) to delete the words ''illegal or otherwise.'' The term ''illegal'' is too broad and could include even a traffic violation. The Contractor's code of business ethics and conduct should cover the types of behavior that this requirement is intended to address.
- The level of background check required depends on the circumstances. This is a business decision, requiring judgment by the contractor.

The source of the FAR clause paragraph (c)(2)(ii)(B) is the USSG Manual paragraph 8B2.1.(b)(3). The Commentary on this paragraph includes this statement: ''With respect to the hiring or promotion of principals, an organization shall consider the relatedness of the individual's illegal activities and other misconduct (*i.e.*, other conduct inconsistent with an effective compliance and ethics program) to the specific responsibilities the individual is anticipated to be assigned and other factors such as: (i) the recency of the individual's illegal activities and other misconduct; and (ii) whether the individual has engaged in other such illegal activities and other such misconduct.''

d. Periodic Review

One respondent asked for an interpretation of the clause paragraph (c)(2)(ii)(C) requirement for periodic review of business practices. For ''monitoring and auditing'', is standard business practice and generally acceptable accounting principals sufficient? What system for assessing the ''risk of criminal conduct'' would be sufficient? Is there a Government program that is an acceptable process?

Response: Standard business practice for ''monitoring and auditing to detect criminal conduct'' which conforms to generally accepted accounting principles should be sufficient. The ''monitoring and auditing'' is amplification of the current FAR requirement for periodic review and auditing, from the FAR case 2006–007 published in November 2007.

One respondent stated that annual audits of research processes may already review compliance with policies for ethical conduct of research funded under Federal contracts. The FAR can acknowledge, through an Alternate to the clause, that duplication of review is not required where reviews under other rules already cover the necessary subjects.

Response: The FAR is not requiring wasted duplication of effort. No change to the regulation is necessary.

3. Mandatory Disclosure to the OIG

Of the 43 respondents that commented on the first proposed rule, 36 commented specifically on sub-paragraph (b)(3) of the clause 52.203–13, Contractor Code of Business Ethics and Conduct, which requires mandatory disclosure, in writing, to the agency OIG, with a copy to the contracting officer, whenever the contractor has reasonable grounds to believe that a principal, employee, agent, or subcontractor of the contractor has committed a violation of Federal criminal law in connection with the award or performance of the contract or any subcontract thereunder.

Six agency OIGs, as well as several Government agencies all specifically concurred with the mandatory disclosure of violations by contractors.

Other respondents, including agency OIGs, while concurring with mandatory disclosure, suggested improvements in the way this requirement is implemented in the rule.

The other 17 respondents that commented specifically on the mandatory disclosure disagreed with this approach and recommended voluntary disclosure.

a. Need for Mandatory Disclosure

Note that the following comments in this section all preceded the enactment of the statute that requires mandatory disclosure, so that the issues are now primarily moot.

i. Major departure from long-standing policy. One respondent stated that this rule is a major departure from long-standing and proven Federal policies that encourage voluntary disclosures. Likewise, another respondent stated that mandatory disclosure runs counter to many established Government processes. One respondent considered the proposed regulation to be a ''sea change'' in the fundamental approach to compliance followed by the Government. Another respondent noted that in 1986 a proposal from DoD to make fraud disclosures mandatory foundered on ''state action'' grounds. In 1988, then Secretary of Defense Richard Cheney withdrew a proposed rule that would have governed such programs on the grounds that ''to be meaningful, corporate codes of conduct must be adopted by contractors voluntarily, not mandated in procurement regulations (54 FR 30911)''. Another respondent also cited a 1996 GAO report on the DoD Voluntary Disclosure Program (GAO/NSIAD–96–21) in which the GAO quotes the DoJ as praising the DoD Voluntary Disclosure Program.

Several respondents cited the DFARS regulations as being a model for voluntary disclosure. Several other respondents stated that many Federal agencies that have considered mandatory disclosure rules have declined to adopt them in favor of voluntary disclosure programs (*e.g.*, Department of Health and Human Services in 2000 (65 FR 40170) and in 2004 (69 FR 46866)).

Response: There is no doubt that mandatory disclosure is a ''sea change'' and ''major departure'' from voluntary disclosure, but DoJ and the OIGs point out that the policy of voluntary disclosure has been largely ignored by contractors for the past 10 years. In addition, in that same time period mandatory disclosure has been adopted for banks and public companies and stressed by the U.S. Sentencing Commission and DoJ, as further discussed in the following sections.

ii. Is voluntary disclosure working? Various respondents stated that the proposed rule fails to demonstrate that there is a need for change based on failure of voluntary disclosure. According to these respondents, neither DoJ nor the Councils have cited data supporting the claim that voluntary disclosure is not effective. One respondent stated that a purported paucity of participants in the DoD IG Voluntary Disclosure Program does not establish a decline in contractor disclosures to the Government sufficient to justify a mandatory disclosure requirement. Another respondent stated that DoJ is comparing the last few years to data from 20 years ago. One respondent cited disclosures for FY 2005–2007 that are relatively level. Another respondent cited the December 2006 issue of Corporate Counsel that voluntary disclosures are increasing rather than decreasing, citing Mr. Mark Mendelssohn of DoJ and a recent report by Sherman & Sterling. Even if there is a decline in disclosure under the DoD Voluntary Disclosure Program, another respondent found that the leap to mandatory disclosure ''gives rise to a perverse implication that justification for mandating regulations can be asserted simply because no one has shown that the activity to be regulated is not happening.''

One respondent stated that the assumptions about the reason for the decrease are misplaced. Another respondent firmly believed that there is need for analysis of the reasons for any decline in voluntary disclosures. Even if mandatory disclosures to the DoD IG Voluntary Disclosure Program are decreasing, several respondents suggested the following possible explanations:

- Less emphasis by DoD.
- Fewer reportable violations.
- More instances resolved as contract matters, with reports to contracting officers or heads of contracting activities or to audit agencies like DCAA and DCMA.
- Perception that the Government is slow in processing voluntary disclosures.
- Lack of restrictions on use of disclosure reports in criminal or civil actions or in administrative actions against individuals.

One respondent elaborated that there may be fewer voluntary disclosures because self-governance is working to prevent and detect contract formation and contract performance issues before they result in criminality or civil fraud. Reduction in the rate of voluntary disclosures would be an expected byproduct of improved internal processes, enhanced training, better internal controls, and an improved culture of ethics and compliance.

One respondent stated that a number of companies have commented that delays in processing disclosures to the OIG are a significant factor in their decision to report problems to the contracting officer instead of to the DoD Voluntary Disclosure Program.

One respondent suggested other avenues for disclosure that are more relevant to the kinds of illegal activity being found these days, such as—

- The DoJ Antitrust Division. Voluntary disclosures to DoJ have increased as disclosures to the DoD IG program have decreased (*see http://www/usdoj.gov/atr/public/speeches/232716.htm#N_1_)*;
- The Department of State Directorate of Defense Trade Controls. This program has been very successful at inducing voluntary disclosures (*see* GAO–05–234 (Feb 2005)); and
- Foreign Corrupt Practices Act. Enforcement actions for violations of the FCPA have also grown, again largely due to voluntary disclosures made by corporations (*see* ''U.S. Targets Bribery Overseas Globalization; Reforms Give Rise to Spike in Prosecutions,'' The Washington Post (Dec 5, 2007)).

One respondent suggested that mandatory reporting should be replaced with a strong voluntary disclosure program modeled after the DoJ Antitrust Division's Corporate Leniency Programs.

Another respondent noted that it is DoJ, not DoD, that apparently believed that the mandatory disclosure provisions were necessary. This respondent interpreted this to mean that DoD is satisfied with the number and types of disclosures being made.

One respondent stated that DoJ should be required to demonstrate that there is an upward trend of criminal prosecutions of the top 100 Government contractors where it was established that contractor principals were aware of violations of the law and made a conscious decision not to disclose those violations to the Government. Similarly, another respondent suggested that DoJ should offer factual support for its thesis that crimes are occurring and being found and yet not being reported voluntarily. One respondent also wanted DoJ to explain why other less burdensome changes, such as improving the existing voluntary disclosure programs, cannot be used to achieve the desired result.

On the other hand, in the DoJ letter of May 23, 2007, DoJ stated that its

experience suggests that few corporations have actually responded to the invitation of DoD that they report or voluntarily disclose suspected instances of fraud. An agency OIG stated that the vast majority of crimes involving contractors that it investigates are not reported by the contractor. Another agency OIG stated that Government contractors are coming forward significantly less frequently with voluntary disclosures. It considered that this mandatory requirement may be the most effective way for the Government to monitor its vendors.

Response: In the DoJ letter dated May 23, 2007, which requested the Administrator of the Office of Federal Procurement Policy, Mr. Paul Denett, to open this case, DoJ states that its experience suggests that few companies have actually responded to the invitation of DoD to report or voluntarily disclose suspected instance of fraud. The respondents do not dispute that relatively few contractors are using the DoD Voluntary Disclosure Program. The contractor groups, in their public comments on the rule, implicitly concede that the Voluntary Disclosure program is not being used and blame DoJ and the OIG. Some claim that informal disclosures are being made to the contracting officers but offer no specific evidence.

Even if it is true that there are comparatively fewer violations now than 20 years ago or that some situations are resolved administratively, there are still significant numbers of violations occurring and being prosecuted that have not been self-disclosed.

Importantly, the incentive to self-disclose Antitrust violations is not applicable. Antitrust deals with the Sherman Act and the Clayton Act, which prohibit conspiracy in restraint of interstate or foreign trade and regulate practices that may be potentially detrimental to competition (price discrimination, exclusive dealing contracts, etc.). Under the Antitrust Division's Corporate Leniency Program, the first company that reports the violation receives immunity from prosecution. That type of circumstance does not apply here.

iii. Existing legal requirements and regulations as models for the rule.

In the DoJ letter of May 23, 2007, DoJ stated that—

- Unlike healthcare providers or financial institutions, there is at present no general requirement that contractors alert the Government immediately as a matter of routine when fraud is discovered;
- DoJ has been careful not to ask contractors to do anything that is not already expected of their counterparts in other industries;
- Our Government's expectations of its contractors has not kept pace with the reforms in self-governance in industries such as banking, securities, and healthcare. Several respondents all considered that for far too long contractors have played by different rules than their counterparts in other industries, such as health care providers and research grant recipients. A Government agency commented that healthcare providers and banks have had such a requirement for many years. An agency OIG commented that in the past 15 years there have been significant reforms in industries such as banking, securities, and healthcare, yet we have not asked the same of Government contractors.

In the DoJ letter of May 23, 2007, DoJ stated that the requested changes are modeled on existing requirements found in other areas of corporate compliance such as the Sarbanes-Oxley Act of 2002 and expand slightly on the Contractor Standards of Conduct in DFARS 203.7000. DoJ also noted that the National Reconnaissance Office (NRO) has begun requiring its contractors to disclose contract fraud and other illegal activities.

a. More far-reaching. However, one respondent stated that the proposed rule imposes substantially more far-reaching and draconian disclosure obligations on Government contractors than those presently made applicable to financial institutions by submission of Suspicious Activity Reports (12 CFR 21.11). The financial institution has to report a crime if the financial institution is an actual or potential victim of the criminal activity. Where a contractor is a victim of a crime committed by an employee or another person, the employee's conduct is not imputed to the contractor. Therefore, the corporation does not incur the risk of criminal liability when it reports an employee violation and is not incriminating itself.

According to another respondent, the current laws and regulations are not sweeping and burdensome, but are specific and narrowly focused. The respondent pointed out that the Anti-Kickback Act and Foreign Corrupt Practices Act limit their mandatory disclosure to a very limited class of activity. The respondent also pointed out that Sarbanes-Oxley contemplates internal reporting mechanisms and review mechanisms at the highest levels before any reporting occurs. The other respondent also addressed the internal control certification required by the Sarbanes-Oxley Act of 2002. Sarbanes-Oxley applies to a contractor that is a public company. Section 302 of Sarbanes-Oxley does not require that a public company disclose to the Government conduct it believes may be a violation of criminal law.

Response: Many of the public comments reveal a basic misunderstanding of the existing mandatory disclosure requirements found in the healthcare, banking, and securities areas. Each requirement effectively mandates disclosure of fraud as broad as the particular regulatory issue being addressed can reach. Beyond that limitation, these other requirements are no more limited than the proposed rule, particularly with the further changes in the final rule with regard to the types of Federal crimes covered.

In particular, the Councils do not agree with the interpretation of 12 CFR 21.11. 12 CFR 21.11 requires financial institutions to report suspicious activities committed or attempted against the bank or involving a transaction or transactions conducted through the bank, where the bank was used to facilitate a criminal transaction.

Even though Section 302 of Sarbanes-Oxley does not require a public company to disclose to the Government conduct it believes may be a violation of criminal law, there are pre-existing securities laws and regulations that require disclosure to the SEC. Sarbanes-Oxley does not provide immunity from prosecution for wrong-doing but provides protection against third-party liability with regard to a lawsuit by the persons accused of wrongdoing.

b. Conforming the FAR? One respondent stated that if the FAR Council is relying on conforming the FAR to regulations applicable to other industries as a justification, the Council should state this explicitly and provide a detailed analysis of the regulations in other areas on which it is relying.

Response: The Councils did not rely on conforming the FAR to regulations applicable to other industries as a justification, but merely cited some parallels. The FAR regulations are designed to suit the particular circumstances of acquisition.

c. Particular public need/statutory basis? One respondent stated that current disclosure programs are not instructive. The respondent also stated that these programs are targeted towards a particular public need, and in most cases are the product of legislation that was enacted in response to a particular public scandal or important national need. In enacting statutory schemes, Congress saw a particular need and targeted legislation to address the particular need (Sarbanes-Oxley, the

Anti-Kickback Act, the Foreign Corrupt Practices Act, and banking laws).

Several respondents were concerned that the same justification does not exist for this proposed rule as the cited statutes and regulations. One respondent stated that the Council has not provided a rational basis to explain why such a significant change to the FAR is necessary. The respondent asserted that the proposed rule could be challenged under the Administrative Procedure Act (APA) because the FAR Council has not provided a ''rational basis'' to justify the mandatory disclosure requirement, nor is there statutory authority behind the FAR Council to issue a regulation providing for mandatory disclosure of criminal acts. The respondent therefore concluded that the FAR Council lacks the authority to issue the regulation (*See AFL/CIO* v. *Kahn, 472 F. Supp. 99 (D.D.C. 1979), rev'd, 618 F. 2d 784* (D.C.Cir. 1979)). One respondent saw this as particularly important in light of DoJ's reliance upon the example of other statutorily-mandated disclosure programs (Sarbanes-Oxley, Foreign Corrupt Practices Act, etc.) as justification for this regulatory initiative. The respondent stated that the mandatory disclosure provisions in the proposed rule are neither the product of specific findings or legislation, nor any perceived critical national need, and thus are not appropriately compared to other existing mandatory disclosure programs.

Response: The DoJ proposed a mandatory disclosure program in order to emphasize the critical importance of integrity in contracting. The public demands honesty and integrity in corporations with which the Government does business. If there is concern that there is not a current public need warranting proceeding with this case, the Councils cite the public outcry over the overseas exemption in the first proposed rule and the recent enactment of the Close the Contractor Fraud Loophole Act (Pub. L. 110–252, Title VI, Chapter 1). The Act requires exactly what the first rule proposed, except that the overseas and commercial item exemptions have been eliminated. However, the rule did not require this legislation in order to have the authority to proceed in this case. The Councils issue rules under the authority of the Office of Federal Procurement Policy Act as well as 40 U.S.C. 121(c), 10 U.S.C. chapter 137, and 42 U.S.C. 2473(c). The Administrator for Federal Procurement Policy may prescribe Governmentwide procurement policies to be implemented in the FAR (41 U.S.C. 405). This case was opened at the request of OFPP. This case is making clear what was already expected. It is not unreasonable or ''capricious'' to require contractors doing business with the Government to disclose violations of the civil False Claims Act (civil FCA) or a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code that have occurred in connection with the award, performance, or closeout of any Government contract performed by the contractor or a subcontract thereunder. Existing DoJ guidelines addressing corporate prosecution standards, while certainly not providing amnesty, suggest that if a company discloses such violations, the prosecution will be of the individuals responsible for the violation, not the entire organization.

d. Empirical support that mandatory disclosure will achieve the Councils' objective. One respondent stated that mandating disclosure without empirical support to show that it will achieve the Councils' objectives will be susceptible to challenge. The APA requires courts to strike down rules devoid of factual support. Another respondent also cited the APA, and that a rule may be set aside if it is arbitrary or capricious (5 U.S.C. 706).

Response: The Councils point to the testimony from DoJ and various OIGs that the experience with the NRO mandatory disclosure clause has been positive (see next paragraph). The Councils further cite the enactment of the Close the Contractor Fraud Loophole Act (see prior section), which now mandates many of these revisions to the FAR.

e. The NRO requirement. An agency OIG noted that similar contractually imposed disclosure requirements have been successfully implemented by the NRO. According to DoJ, the NRO reports that this requirement has improved its relationships with its contractors and enhanced its ability to prevent and detect procurement fraud. Another agency OIG stated that adoption of the NRO clause resulted in increased and earlier disclosure of wrongdoing and better working relationships built upon greater sharing of information and trust. It also led to the conclusion that it is more effective for a contractor to mandatorily disclose information pursuant to a requirement, than it is for a contractor to be in a position of offering up information that it could be criticized, or even sued, for providing.

One respondent, however, stated that the NRO requirement is not an appropriate model for all Government contractors because it requires disclosure of potential illegal activity related to the conduct of intelligence operations in the interest of national security and thus is not instructive. In fact, according to another respondent, the unique nature of the NRO and its responsibilities are major reasons cited as justification for its disclosure program. Similarly, the other respondent stated that, while the NRO's mandatory disclosure program was not the product of legislation, it was the direct product of an obvious and public awareness that we live in a different world after September 11, 2001.

Furthermore, several respondents cited problems with the NRO disclosure program. One respondent stated that ''it is far from clear at this point whether the NRO mandatory disclosure program is or will be productive'', citing anecdotal reports from the contractor community suggesting that the program is not as effective as the NRO claims. One respondent cited problems experienced by contractors subject to the NRO OIG reporting clause, claiming that the NRO OIG has inserted itself in the administration of contracts by using the clause as the basis to become involved in all aspects of the contractor ethics functions and corporate investigations. For example, the respondent stated that the OIG has used this clause to investigate, as a Federal offense, matters as mundane as employees who have been disciplined for leaving work early while reporting they were present. The respondent does not believe that OIG agents should be routinely involved in company internal ethics functions and contract administration. The respondent quoted Mr. Paul Denett, Administrator of the Office of Federal Procurement Policy: ''The IG serves a purpose, but it needs to be limited to core areas.''

However, the response from the National Procurement Fraud Task Force (NPFTF), signed by the IG of the NRO, stated that the requirement for mandatory reporting has worked very well at NRO: The reporting of wrongdoing has increased, comes earlier, and has led to a good working relationship. NPFTF considers that this model can have a similar impact across the Federal Government, and that the situation at NRO is not unique.

Response: Almost all the agency OIGs submitting public comments cite the success of the clause initiated by the NRO OIG as a reason for supporting this rule for their agency procurements.

As to limiting the role of the OIG to its core area, the core area of the OIG is to investigate fraud, conflict of interest, bribery, and gratuity violations. OIG agents will not be routinely involved in company internal ethics functions and

contract administration unless violations are disclosed. The final rule has been revised to more closely focus the situations that must be disclosed by limiting violations of criminal law to violations involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code (see B.3.b.iii.).

iv. Will mandatory disclosure make reporting easier or better? In the DoJ letter of May 23, 2007, DoJ stated that if the FAR were more explicit in requiring such notification, it would serve to emphasize the critical importance of integrity in contracting. An agency OIG stated that the requirement will simplify the contractors' decision on whether to disclose suspected violations. Likewise, another agency OIG stated that the contractor is in a stronger position when reporting for the purpose of complying with a mandatory requirement than if voluntarily disclosing information, for which it could be criticized, or even sued. Another agency OIG commented that making self-reporting a requirement gives the honest contractor employees necessary leverage over those who may seek to shield the employer when wrongdoing is noticed or suspected.

On the other hand, some other respondents believed that if employees know that everything they report will be passed on to the Government, this may result in less reporting up the chain of the company rather than more. One respondent saw substantial potential to decrease rather than enhance cooperation with company compliance efforts.

The respondent was concerned that the likelihood of severe consequences will necessarily change the relationship of the company and its employees. Every interview will have the potential of resulting in employees being reported. It may be that investigative targets may not only be entitled to counsel, but to Miranda warnings, if the company is deemed to be acting on behalf of the Government. Further, another respondent was concerned that mandatory reporting may violate existing contracts with a labor union and may be an unfair labor practice if imposed without bargaining, citing *American Elec. Power Co.,* 302 NLRB 161(1991). Resistance by the employees can undercut the entire compliance program. A respondent also believed that employees may be reluctant to come forward if they are aware that the contractor will be required to report their co-workers, or report the company itself, to the OIG. This respondent cited studies by the framers of the USSG who undertook significant research addressing these issues.

Response: The Councils believe that by mandating disclosure, contractor executives and their counsel will be more inclined to make the required disclosure to the OIG, as opposed to either not disclosing or informally alerting the contracting officer, who is not in a position to evaluate the criminal behavior of individual employees. By mandating disclosure to the OIG, the rule will add weight to the arguments inside a corporation that good business practices in the long run favor compliance and disclosure. Nothing in the proposed rule requires administration of ''Miranda'' warnings. The rule does not place contractors in the role of law enforcement officers. With regard to the concerns about labor agreements, contractors can find ways to disclose without violating labor union provisions that protect individual privacy of workers.

v. Cooperative atmosphere more effective. According to one respondent, voluntary disclosure fosters a cooperative environment and rewards contractors that adopt effective internal controls. Another respondent considered that it is a key principle to promote self-governance as the preferred model to ensure compliance. This respondent quoted the Packard Commission findings in June 1986 that self-governance is the most promising mechanism to foster improved contract compliance. Self-governance makes the difference between responsibility for compliance and a mere facade of compliance. This respondent concluded that, based on 20 years of experience, both scholars and industry leaders believe that the current system of voluntary disclosure encourages companies to develop a stronger culture while still affording the Government broad remedies to protect the Government's interests. Under mandatory disclosure, contractors may focus on the ambiguities of the letter of the rule rather than the spirit of mutual commitment. One respondent expressed long standing support for and experience with voluntary self-reporting. It is concerned that mandatory self-reporting could discourage partnerships with the Government. One respondent cited the ''fundamental principle'' that contractor compliance programs resulting from internal company commitments to ethical behavior are more likely to be effective in preventing illegal behavior than programs imposed by ''overbearing regulations.''

Response: The Councils disagree. See ''Is voluntary disclosure working?'' at paragraph B.3.a.ii.

vi. Incentives. Several respondents contended that existing Government programs and contractor initiatives offer ample incentives for contractors to voluntarily report procurement violations.

- Several respondents pointed out that contractors may receive favorable consideration in debarment proceedings if they have voluntarily disclosed the conduct in question.
- Several respondents cited the civil FCA, which provides contractors with an incentive to report potentially fraudulent behavior. Organizations will voluntarily disclose to avoid lengthy and costly whistleblower litigation (*qui tam* actions). According to several respondents, voluntary disclosure can undermine a court's jurisdiction to entertain future *qui tam* cases and can mean the difference between maximum and reduced penalties.
- Several respondents also addressed the reduced penalties under the guidelines of the USSG, adopted in 1991, which are predicated on a model of rewarding voluntary reports. Two respondents stated that the proposed rule is inconsistent with the favorable treatment of voluntary disclosures under the USSG.
- Respondents cited the Deputy Attorney General's January 20, 2003, memorandum, ''Principles of Federal Prosecution of Business Organizations,'' which provides to Federal prosecutors guidance governing charging decisions with respect to corporations and sentencing. Several respondents also cited Deputy Attorney General Paul J. McNulty's memorandum of December 12, 2006, which demonstrated that the DoJ considers an organization's voluntary disclosure and cooperation in determining whether to bring charges.

Various respondents were concerned that the proposed rule may eliminate the ability of a contractor to claim the benefit of ''timely and voluntary disclosure'' to the Government. One respondent recommended that, if the rule is finalized, a contractor should not be precluded from seeking and receiving leniency because a disclosure is made in compliance with the rule. One respondent stated that the proposed rule is not more consistent with the USSG, but actually contradicts them.

One respondent stated that the Councils must consider these concerns and evaluate the extent to which eliminating incentives to voluntary disclosure will affect a contractor's decision to disclose underlying behavior. The respondent believed that

eliminating incentives could cause contractors to adopt a protective posture in the face of evidence of potential criminal behavior.

Another respondent suggested that, instead of mandating compliance and ethics programs, the Councils should open a new FAR case to develop an incentive-based approach. This respondent was concerned that the logic of penalizing contractors for failure to disclose a crime, rather than offering incentives, will not work. The disclosure obligation applies only if a crime has already occurred. If there is already a crime, then the company is already subject to punishment. Failure to disclose will only be an aggravating factor. So, if a company fails to disclose, it may escape punishment, but if it discloses, it will likely still be subject to punishment for the crime committed. Therefore, punishment for failure to disclose may not be sufficient incentive to disclose.

Response: There is nothing in this rule that removes any of the existing incentives. The incentives in the FAR (FAR 9.406–1(a)) and the USSG are not limited to ''voluntary'' disclosures but to ''disclosures.'' Even if disclosure is ''mandatory,'' incentives will still be offered to promote compliance.

b. Vagueness of Rule

i. ''Reasonable grounds to believe.'' Numerous respondents were concerned that the rule does not specify what constitutes ''reasonable grounds.'' One respondent stated that ''reasonable grounds'' is subject to varying interpretations, and may be viewed as an even lower standard than ''probable cause.'' Should the contractor report based on mere suspicion or based on evidence that criminal activity has occurred? Because of this lack of clarity, several respondents were concerned that companies may tie up Government resources with a mountain of meaningless legal trivia. Numerous respondents stated that there will be substantial over-reporting because contractors may report even remotely possible criminal conduct out of an abundance of caution. One respondent considered that this will raise company costs through the investigation of baseless claims and incidents. Several other respondents stated that there will be an enormous amount of time spent sorting out the true criminal activity and truly significant problems.

One respondent suggested that the proposed rule will potentially subject an employer to civil actions brought by an employee when the reports forwarded by the employer to the Federal Government (because conceivably ''reasonable grounds'' existed) ultimately are determined to lack merit.

Response: The Councils have replaced ''reasonable grounds to believe'' with ''credible evidence.'' DoJ Criminal Division recommended use of this standard after discussions with industry representatives. This term indicates a higher standard, implying that the contractor will have the opportunity to take some time for preliminary examination of the evidence to determine its credibility before deciding to disclose to the Government. See also the following discussion of ''timely disclosure.''

ii. Timely disclosure.

There are 3 aspects of timely disclosure that are of concern to the respondents:

- To which violations/contracts does timely disclosure apply?
- How much time does a contractor have to disclose a possible violation after first hearing something about it?
- How do we transition into this rule? How is timeliness measured for violations that the contractor may already know about and did not disclose prior to becoming subject to this rule?

Further, in analyzing these issues, there are 3 separate requirements for timely disclosure in this rule which may affect the response to the above questions:

- The contract clause requirement to disclose (paragraph (b)(3)).
- The contract clause requirement for an internal control system (paragraph (c)(2)(ii)(F)).
- Failure to timely disclose as a cause for suspension/debarment regardless of requirement for contract clause or internal control system (Subpart 9.4).

a. To which violations/contracts does timely disclosure apply?

Various respondents were concerned about whether the rule can apply to violations that occurred before the effective date of the rule, the date of the bid, or the date the clause is incorporated into the contract.

- Effective date of the rule. Numerous respondents recommended that the rule be made applicable only to conduct occurring on or after the date the rule is effective. The respondents argued that there is presently no requirement in the FAR for a contractor to disclose to the Government criminal violations committed by its employees. The respondents cited case law to support the argument that application of the rule to conduct occurring before the rule effective date would be impermissible. One respondent stated that the reporting requirement should be ''prospective only''. Otherwise this requirement may impose an unreasonable burden.
- Date the clause is incorporated. Another respondent questions whether the rule is meant to cover past acts, or only acts going forward from the date the clause is incorporated into a contract. According to one respondent, to punish entities for past acts would violate constitutional ex post facto prohibitions.
- Date of the bid. One respondent suggested that the violation would have to occur after the date of the bid.

Several respondents also looked at the end of the period during which violations that occur must be reported. One respondent suggested that completion of performance would be appropriate.

DoJ suggested limiting the mandatory disclosure of overpayments or criminal violations to matters discovered by the contractor within three years after contract completion.

Response: The first significant point to remember is that in all cases the reportable violations are linked to the performance of Government contracts. In the case of the contract clause direct requirement for contractor disclosure, the reportable violations are limited to the contract containing the clause. So the questions raised by the respondents about occurrence of violations are not an issue with regard to the contract clause disclosure requirement, because violations would necessarily occur during award or performance of the contract, through contract closeout, which would necessarily be after the effective date of the rule and after incorporation of the clause. (**Note:** The clause will be included in solicitations and resultant contracts after the effective date of the rule, in accordance with FAR 1.108(d)).

However, in the case of internal control systems and suspension/debarment, the proposed rule states that reportable violations could occur in connection with ''any Government contract.'' This could be overly broad in two regards—

- Does it apply to violations on the contracts of other contractors?
- Does it apply to contracts closed out 20 years ago?

The Councils have made clear in the final rule that this disclosure requirement is limited to contracts awarded to the contractor (or subcontracts thereunder). It was not the intent of the proposed rule to require contractors to report on violations of other contractors under contracts unrelated to their own contracts.

The Councils do not agree with the respondents who think that disclosure under the internal control system or as a potential cause for suspension/

debarment should only apply to conduct occurring after the date the rule is effective or the clause is included in the contract, or the internal control system is established. The laws against these violations were already in place before the rule became effective or any of these other occurrences. This rule is not establishing a new rule against theft or embezzlement and making it retroactive. The only thing that was not in place was the requirement to disclose the violation. If violations relating to an ongoing contract occurred prior to the effective date of the rule, then the contractor must disclose such violations, whether or not the clause is in the contract and whether or not an internal control system is in place, because of the cause for suspension and debarment in Subpart 9.4.

However, the Councils agree that this requirement should not stretch back indefinitely into the past (*e.g.*, contracts that were closed 20 years ago). At that point, relevance with regard to present responsibility has diminished, there is less availability of evidence to support an investigation, there is more difficulty locating the responsible parties (who is the contracting officer?), and there should be some reasonable limitation on a contractor's liability after contract closeout.

The Councils considered using contract closeout as the end point for the requirement to disclose fraud, but according to the DoJ, often contract fraud occurs at the time of closeout, and cutting off the obligation to disclose at that point would exempt many of these violations from the obligation to disclose. Three years after final payment is consistent with most of the contractor record retention requirements (*see* Audit and Records clauses at FAR 52.214–26 and 52.215–2). Therefore, the Councils concur with the DoJ recommendation that the mandatory disclosure of violations should be limited to a period of three years after contract completion, using final payment as the event to mark contract completion.

Therefore, the Councils have added the phrase ''Until 3 years after final payment on any Government contract awarded to the contractor'' at 9.406–2(b)(1)(vi) and 9.407–2(a)(8), and has added in the clause at paragraph (c)(2)(ii)(F) the statement that ''The disclosure requirement for an individual contract continues until at least 3 years after final payment on the contract.'' To make the applicability during the close-out phase of a contract clearer, the Councils have revised the draft final rule in all applicable places to refer to ''award, performance, or closeout.''

b. Does ''timely'' allow sufficient time between first learning of the allegation and the disclosure?

One respondent objected that ''timely'' is very broad in scope which could permit contracting officers to have inconsistent interpretations of what is timely. One respondent questioned whether ''timely'' means upon first learning of an allegation or only upon conducting an adequate internal investigation. The respondent recommended that the regulations should include a set period of time (*i.e.*, 90 days) for any reporting requirement. Another respondent recommended that the regulations might allow 60 days to determine if there are reasonable grounds to conclude that the contractor committed a crime. The 60 day period would start when a principal of the company suspects that a crime might have been committed, but lacks reasonable grounds for concluding that a crime has been committed. An agency OIG suggested ''timely'' should be replaced with ''within 30 calendar days.''

Another respondent was concerned that when ''timely'' disclosure must occur is ambiguous because the timing of a violation is troublesome. Contractors often settle cases without any admission of fault or liability. The rise in deferred and non-prosecution agreements in criminal cases brought by the Government against contractors creates confusion regarding disclosure of criminal violations.

According to many respondents, the proposed rule may require premature reporting. One respondent questioned the requirement to notify without delay, whenever the contractor becomes ''aware'' of violations of Federal criminal law. According to this respondent, the rule does not clarify what constitutes ''awareness.'' Several other respondents were concerned that the proposed amendment does not appear to allow a contractor to complete an internal investigation before notifying the OIG and contracting officer. Several respondents considered that an internal investigation could be compromised by premature reporting. One respondent recommended that the rule should allow the contractor the opportunity to comply with its ethics and compliance program and conduct an internal investigation prior to disclosure to the Government. Contractors should be required to report only actual violations of law, not those incidents that have not been confirmed as actual violations.

One respondent pointed out that existing voluntary disclosure protocols allow for internal investigation by the reporting parties before a disclosure is made. Another respondent stated that under the DoD Voluntary Disclosure Program, if the preliminary investigation reveals evidence to suggest that disclosure is warranted, contractors may disclose information sufficient for preliminary acceptance into the DoD Voluntary Disclosure Program, and then have 60 days to complete a fuller investigation. This rule provides no guidance on preliminary steps afforded to a contractor.

One respondent also recommended that the contractor be explicitly provided with a reasonable period of time to internally investigate a potential violation.

DoJ suggested that the preamble to the final rule should make clear that nothing in the rule is intended to preclude a contractor from continuing to investigate after making its initial disclosure to the Government. DoJ would expect that the OIG or the contracting officer will encourage the contractor to complete its internal investigation and make full report of its findings.

In their comment on the second proposed rule, one respondent recommends that the preamble should explain that a contractor, with the contracting officer's approval, may tailor the ''timely reporting'' provision of its internal control system in order to make meaningful reports to the contracting officer.

Response: First, the Councils note that the new statute uses the term ''timely'' in setting forth disclosure requirements. The Councils considered, and rejected, adding a set period of time, *e.g.*, 30 days, to the disclosure requirement. It was decided that doing so would be arbitrary and would cause more problems than it would resolve, *e.g.*, how to determine when the 30 days begins.

Further, the Councils believe that using the standard of ''credible evidence'' rather than ''reasonable grounds to believe'' will help clarify ''timely'' because it implies that the contractor will have the opportunity to take some time for preliminary examination of the evidence to determine its credibility before deciding to disclose to the Government. Until the contractor has determined the evidence to be credible, there can be no ''knowing failure to timely disclose.'' This does not impose upon the contractor an obligation to carry out a complex investigation, but only to take reasonable steps that the contractor considers sufficient to determine that the evidence is credible.

The Councils note that there is no rigidness to our proposed requirement to establish an internal control system. The rule just sets forth minimum requirements. The contractor can use its own judgment in the details of setting up a system that meets the minimum requirements. The clause does not require contracting officer approval of this system.

c. Transitioning into the rule. Meaning of ''timely'' when the knowledge of credible evidence pre-dates the requirements of this rule. One respondent stated that the reporting requirement should be ''prospective only''. Otherwise this requirement may impose an unreasonable burden.

Response: As just discussed, the disclosure requirement is prospective only. Although violations on the current contract might have occurred during the pre-award phase and violations on other contracts may have already occurred prior to establishment of the internal control system or prior to the effective date of the rule, timely disclosure of the violation can only be measured from the time when the requirement to disclose the violation came into effect, even if credible evidence of the violation was previously known to the contractor.

With regard to the contractual disclosure requirement, the timely disclosure would be measured from the date of determination of credible evidence or the date of contract award, whichever event occurs later.

With regard to the disclosure requirement of the internal control system, it can only become effective upon establishment of the internal control system. The violation can have occurred with regard to any Government contract which is still open or for which final payment was made within the last 3 years, so may predate establishment of the internal control system. Therefore, timely disclosure of credible evidence as required by the internal control system would be measured from the date of determination by the contractor that the evidence is credible, or the date of establishment of the internal control system, whichever event occurs later.

With regard to the knowing failure by a principal to timely disclose credible evidence of a violation or significant overpayments as a cause for suspension or debarment, the violation can have occurred with regard to any Government contract, which is still open or for which final payment was made within the last 3 years, so may predate the effective date of the rule. Therefore, timely disclosure of credible evidence as required by the rule as a cause for suspension or debarment would be measured from the date of determination by the contractor that the evidence is credible, or from the effective date of the rule, whichever event occurs later.

To some extent, the effective date of the rule actually trumps the other events, because the failure to timely disclose as a cause for suspension/debarment is independent of the inclusion of the contract clause in the contract or the establishment of an internal control system. At least in those instances where disclosure was not timely in regard to effective date of the rule, but was reported as soon as the clause was in the contract, or as soon as the control system was in place, then it would not be a violation of the contract or a mark against the control system. It could still be a cause for suspension or debarment, although the Councils consider that suspension or debarment would be unlikely, if the contractor came forward as soon as the clause or the internal control system was in place (before that, the contractor might have been unaware of the requirement to disclose).

iii. ''Criminal violation in connection with contract award or performance.'' Numerous respondents stated that the rule fails to specify what constitutes a ''criminal violation'' ''in connection with contract award or performance''. Some of these respondents made the following comments:

- The broad nature of the phrase ''violation of Federal criminal law in connection with contract award or performance'' places a heavy burden. The Government is in the best position to provide specific guidance to contractors as to the violations that would be considered covered by this new requirement. Otherwise, each contractor will have to develop its own list and explanations to its employees as to what constitutes criminal violations.
- If the FAR Council proceeds with the rule, it should provide a specific list of the criminal violations that the contractor is required to disclose.
- The self-reporting requirements should be revised to provide the specific circumstances under which self-reporting is required.
- The provision is vague in regard to the type of ''criminal violation'' covered, leaving open application of the rule to non-procurement related offenses. If an employee commits a criminal violation while driving on Federal lands in the course of performing a contract, must the traffic violation be reported to the agency OIG? Also, the agency OIGs may receive reports about violations of Federal tax law or Occupational Safety and Health laws that occur in connection with the performance of the contract, over which the OIGs do not have jurisdiction. This can result in unnecessary or inappropriate reports.
- The proposed rule does not elaborate on the nexus between the perceived criminal conduct and the Federal contract so as to trigger the reporting requirement. A contractor's silence could be alleged to be a false statement where the employer had ''reason to believe'' that one of its employees, agents, or subcontractors had violated criminal law in connection with a contract.
- The rule should define more clearly what is reportable and when the obligation to report is triggered.

One Government agency suggested adding ''potential'' to ''violation.''

DoJ also suggested tightening the standard for disclosure by adding the phrase ''involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code.''

Response: The Councils have adopted the more specific description of criminal law suggested by DoJ as responsive to many of the concerns expressed by the respondents.

As to nexus with the contract, the clause stipulates in paragraph 52.203–13(b)(3)(i) that the violation should have occurred ''in connection with the award, performance, or closeout of this contract, or any subcontract thereunder.'' With regard to the internal control system disclosure required in paragraph 52.203–13(c)(2)(ii)(F) and the cause for debarment or suspension in Subpart 9.4, the violation must be in connection with the award, performance, or closeout, of any Government contract performed by the contractor, or a subcontract thereunder, and the obligation to disclose information lasts until 3 years after final payment. If there is no connection to a Government contract performed by the contractor, or a subcontract thereunder, then it need not be disclosed.

The Councils do not consider it necessary to add ''potential'' to ''violation'' because that preceding language already is in terms of ''credible evidence.'' That does not necessarily mean that a violation has occurred, but the principals are looking for ''credible evidence'' that a violation has occurred. ''Potential violation'' would open it even wider and could result in too many unnecessary disclosures.

iv. Level of employee with knowledge. Several respondents wanted the rule to identify the level of contractor employee whose knowledge will be imputed to the contractor, such that the contractor has the requisite

knowledge. Absent such identification, consistent with the doctrine of *respondeat superior* applied in Federal criminal law, a contractor may be deemed to have requisite knowledge warranting disclosure if any employee at any level is aware of conduct which may constitute a Federal criminal offense. This could cause a contractor to be accused of violating the mandatory disclosure provision before the contractor's management becomes aware of the offense and before the appropriate steps for disclosure may be undertaken. One respondent stated that it is unreasonable to expect all knowledge to be passed up the chain. Several respondents recommended revision of the proposed rule to require that a contractor principal must have the requisite knowledge of a Federal criminal law violation before that knowledge will be imputed to a contractor.

Response: The Councils concur that for debarment and suspension, a principal must have the requisite knowledge in order for mandatory disclosure to be applicable. See response under the heading ''Suspension/Debarment'', ''Who has knowledge?'' at paragraph B.5.e.

c. Disclosure to OIG. One respondent considered that the proposed rule would essentially require contractors and subcontractors to become fraud detection and reporting entities. Must contractors become experts in forensic accounting and private investigation? This respondent considered that the proposed rule essentially would ''deputize'' contractors and subcontractors as agents of the OIG. One respondent also considered that the company is now acting as an agent of the Government.

Is ''the agency OIG'' the OIG for the agency which awarded the contract under which the action in question took place? One respondent was concerned when contractor is required to disclose to different inspectors general because the proposed rule is silent on what actions and procedural safeguards are to be implemented in the various offices of the Inspectors General. A contractor that deals with a variety of different Federal agencies will unreasonably be faced with significantly increased risk and uncertainty.

Several respondents considered that a likely outcome of the mandatory reporting to the agency OIG will be to remove from a contracting officer or agency the authority or the ability to settle and compromise the issues by a disclosure. One industry association indicated that member companies report that in their experience, the vast majority of potential violations disclosed to a contracting officer or other agency official are quickly resolved as an administrative matter. Once a matter is referred to the DoD OIG as a potential criminal or civil fraud matter, under the Contract Disputes Act the contracting officer loses his or her ability to compromise or settle the issue. One respondent was also concerned about the impact of the proposed rule on the influence and authority of the contracting officer. The respondent considered that disclosure to the OIG passes the leadership role on any subsequent investigation and review to the OIG's office and undercuts the authority and ability of the contracting officer to manage contracts.

One respondent noted that under the DFARS rule, the OIG only needs to be notified when appropriate. One respondent considered that mandatory notification to the OIG defeats the concept of internal audits and correction of possible irregularities. The respondent is concerned that, once the OIG is brought into the process, both the contracting officer and the contractor/subcontractor lose control of the process.

One respondent was concerned with the ability of the OIG to handle an increased level of reports. One respondent stated that their experience with the capability of the OIG's offices to deal with complicated, sophisticated and/or fact-intensive issues is very mixed at best. Current demands have placed substantial strain in the ability of the OIG's offices to support investigations, and delays are commonplace. ''According to the respondent, 'competing demands for resources to support overseas investigations and Homeland Security defense have drained whatever experienced resources existed'' at the agency OIGs.

An agency OIG suggested replacing ''agency Office of the Inspector General'' with ''A President-selected and Senate-approved Inspector General or designated Federal entity Inspector General.'' The agency OIG stated that this better describes the correct agency to which the contractor should report potential violations.

Response: There is nothing in the proposed rule that ''deputizes'' contractors. The Councils have concluded that it is appropriate for contractors to send the reports directly to the OIG, with a copy to the contracting officer, because it is the OIG that is responsible for investigating the disclosure.

The disclosure would be to the OIG of the agency that awarded the subject contract. The Councils have added clarification that if a violation relates to more than one Government contract, the Contractor may make the disclosure to the agency OIG and Contracting Officer responsible for the largest dollar value contract impacted by the violation. If the violation relates to an order against a Governmentwide acquisition contract, a multi-agency contract, a multiple-award schedule contract such as the Federal Supply Schedule, or any other procurement instrument intended for use by multiple agencies, the contractor shall notify the OIG of the ordering agency and the IG of the agency responsible for the basic contract.

Whether OIGs can handle an increase in the level of reporting depends on the expected level of increase. The Councils do not anticipate that companies are going to flood the OIG with trivialities, as some respondents fear. The Council also notes that the agency OIGs were all strongly in favor of this rule.

The Councils do not agree with the suggestion of one agency IG that the rule should specify ''A President-selected and Senate-approved Inspector General or designated Federal entity Inspector General.'' Although this is probably accurate, the Councils consider it too complicated for some contractors to determine. It is the opinion of the Councils that, if a contractor submits a report to the wrong OIG, that OIG will forward it to the appropriate OIG.

Throughout the rule, the Councils have used the words ''disclose'' and ''disclosure'' for consistency, rather than in some places using the word ''notify'' or ''report''.

4. Full Cooperation

The proposed rule states at paragraph (c)(2)(ii)(G) of FAR 52.203–XX (now 52.203–13) that a contractor Code of Business Ethics and Conduct shall, at a minimum, have an internal control system that provides ''full cooperation with any Government agencies responsible for audit, investigation, or corrective actions.''

a. Waiver of Privileges/Protections/Rights

Many respondents expressed concern that compliance with the rules requiring disclosure and full cooperation would be interpreted to—

- Require contractors waive an otherwise valid claim of attorney-client privilege or protections afforded by the attorney work product doctrine, both protecting attorney-client communications; or
- Interfere with an employee's right under the Fifth Amendment of the U.S. Constitution covering the right of an

individual not to be compelled to incriminate itself.

One respondent recommended addition of strong language to preserve privilege protections.

DoJ and an agency OIG indicated awareness of these concerns in their comments and recommended clarification in the final rule. DoJ proposed that the final rule state explicitly:

''Nothing in this rule is intended to require that a contractor waive its attorney-client privilege, or that any officer, director, owner, or employee of the contractor, including a sole proprietor, waive his or her attorney-client privilege or Fifth Amendment rights.''

Response: It is doubtful any regulation or contract clause could legally compel a contractor or its employees to forfeit these rights. However, the Councils have revised the final rule to provide such assurance. To address concern that cooperation might be interpreted to require disclosure of materials covered by the work product doctrine, the Councils have added a definition of ''full cooperation'' at 52.203–13(a) to make clear that the rule does not mandate disclosure of materials covered by the attorney work product doctrine.

For comparison purposes, it is instructive to refer to the flexible approach adopted in the USSG:

> Waiver of attorney-client privilege and of work product protections is not a prerequisite to a reduction * * * unless such waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization.

It also is worth pointing out the DoD Voluntary Disclosure Program never required waiver as a condition of participation. Contractors in that program routinely found ways to report wrongdoing without waiving the attorney-client privilege or providing their attorney memoranda reflecting their interviews that normally are covered by the work product doctrine.

Any limitation in this rule should not be used as an excuse by a contractor to avoid disclosing facts required by this rule. Facts are never protected by the attorney-client privilege or work product doctrine. Moreover, the Fifth Amendment has no application to corporations, so the only sensitive area is mandatory disclosure or cooperation by individuals or sole proprietors, which is addressed in the clarification.

b. Indemnification of Employees

Several respondents expressed concern that full cooperation will be interpreted as prohibiting a contractor from indemnifying its employees or their individual counsel to the extent permitted or required by state law or the contractor's charter or bylaws. Several respondents expressed concern that the Government may view indemnification of contractor employees as not cooperating. One respondent asked if there was a difference between ''cooperation'' and ''full cooperation'' and, more seriously, whether full cooperation restricted a contractor's ability to make counsel available to its employees. Several respondents pointed to the district court opinion in *U.S.* v. *Stein,* 435 F.Supp. 2d 330 (SDNY 2006), and 440 F.Supp. 2d 315 (SDNY 2006) that suggests the Government viewed KPMG's practice of paying for employees' legal costs pursuant to indemnification rules was not ''cooperation'' favored by the prosecutors in that case.

Response: With regard to indemnification of employees for legal costs, State law—not Federal—controls. Just as full cooperation cannot mean a company forfeits its attorney-client privilege, there is no reason to think it means employees forfeit their right to indemnification from their employers. On December 12, 2006, DOJ addressed this issue in a memorandum sent to all DoJ attorneys by Deputy Attorney General Paul McNulty (''McNulty Memorandum''), stating:

> Prosecutors generally should not take into account whether a corporation is advancing attorneys' fees to employees or agents under investigation and indictment. Many state indemnification statutes grant corporations the power to advance the legal fees of officers under investigation prior to a formal determination of guilt. As a consequence, many corporations enter into contractual obligations to advance attorneys' fees through provisions contained in their corporate charters, bylaws or employment agreements. Therefore, a corporation's compliance with governing state law and its contractual obligations cannot be considered a failure to cooperate.

c. Requirement to Fire an Employee

One respondent asked that the rule clarify that cooperation does not mean a contractor must fire an employee.

Response: It is inappropriate for the Government to direct a contractor to fire an employee, although the Government may require that an employee be removed from performance of the Government contract. However, most corporate compliance programs assert that violation of law or company policy is grounds for dismissal. Also note the internal control system requirements for principals at paragraph (c)(2)(ii)(B) of the clause.

d. Ability To Conduct a Thorough and Effective Internal Investigation

Several respondents expressed concern that cooperation or disclosure will be interpreted to interfere with a contractor's ability to conduct a thorough and effective internal investigation. Some respondents were concerned that a contractor continuing to investigate a matter after reporting would be deemed not cooperating. One respondent recommended that the rule state explicitly that: ''A contractor has a reasonable time to investigate a potential investigation * * * and that nothing in the rule prohibits or restricts a contractor from conducting an internal investigation.''

Response: Any interpretation of full cooperation that would suggest a limit on contractors conducting internal investigations would be clearly at odds with the intent of the rule, which encourages compliance program investigations, reporting, and cooperation.

e. Defending a Proceeding or Dispute Arising From or Related to Disclosure

Various respondents expressed concern that full cooperation will be interpreted to preclude a contractor from defending itself in a proceeding or dispute arising from or related to the disclosure. One respondent raised concerns that a rule mandating full cooperation could be interpreted as prohibiting a contractor from ''vigorously defending its actions.'' Another respondent observed that full cooperation might require a contractor to waive its right to appeal the results of an audit.

Response: Nothing in the rule would foreclose a contractor from advancing a defense or an ''explanation'' for the alleged fraud or corruption arising in a Government contract. This includes being free to use any administrative or legal rights available to resolve any dispute between the Government and the contractor. The rule is intended simply to require the contractor to be forthcoming with its customer, the Government, with regard to credible evidence relating to alleged fraud or corruption in its Government contracts.

f. Expansion of Audit Rights and Access to Records

Various respondents asked to what extent full cooperation overrode the limits on Government audit rights and access to records limitations, giving the Government ''unfettered access'' to individuals to conduct interviews, even though the current audit access clauses are limited to documents. Expanding on

that, one respondent also asked if the rule requires contractors to give the Government ''full access to their financial and proprietary information, beyond that required by existing contract clauses.'' Another respondent also observed that the Government may invoke the requirement in connection with disputes before the Board of Contract Appeals or U.S. Court of Federal Claims. One respondent requested clarification that the cooperation requirement applies only to agencies affected by the conduct and not the entire Government.

Response: The proposed rule was not intended to have any application or impact on the Government's exercise of its audit and access to records rights in the routine contract administration context except as the issue arises when a contractor discloses fraud or corruption or the Government independently has evidence sufficient to open an investigation of fraud and solicit the contractor's cooperation. The issue of contractor cooperation in this rule arises primarily in the context of Government investigation of contract fraud and corruption and any application of this rule in any other context by the Government would be clearly overreaching.

g. Inadvertent Failure as Non-Cooperation

One respondent feared that an ''inadvertent'' failure to provide documents in a routine DCAA audit would be deemed non-cooperative.

Response: The rule has no application to routine DCAA audits.

h. Need for Definition

Many respondents asked for an expanded definition of ''full cooperation'' in order to reduce the potential for misinterpretation of the rule, resulting in the concerns addressed in the preceding paragraphs.

Response: Contractors are not expected to block Government auditors and investigators' access to information found in documents or through its employees in furtherance of a contract fraud or corruption investigation.

Generally speaking, it is also reasonable for investigators and prosecutors to expect that compliant contractors will encourage employees both to make themselves available and to cooperate with the Government investigation.

That also applies to responding to reasonable Government requests for documents. Ignoring or offering little attention to detail in responding to auditor or investigator requests or subpoenas for documents or information may, in some circumstances, be obstruction of justice and, if established, certainly would not be deemed full cooperation.

According to the USSG, cooperation must be both timely and thorough:

- To be timely, the cooperation must begin essentially at the same time as the organization is officially notified of a criminal investigation.
- To be thorough, the cooperation should include the disclosure of all pertinent information known by the organization.

—A prime test of whether the organization has disclosed all pertinent information is whether the information is sufficient for law enforcement personnel to identify—

—The nature and extent of the offense; and

—The individual(s) responsible for the criminal conduct.

—However, the cooperation to be measured is the cooperation of the organization itself, not the cooperation of individuals within the organization. If, because of the lack of cooperation of particular individual(s), neither the organization nor law enforcement personnel are able to identify the culpable individual(s) within the organization despite the organization's efforts to cooperate fully, the organization may still be given credit for full cooperation.

The DoD Voluntary Disclosure Program described expected cooperation in some detail in its standard agreement (the ''XYZ Agreement''), and it may be a useful reference in this circumstance where the contractor discloses credible evidence of fraud or corruption under this rule. However, the detail found there goes significantly beyond the scope of this rule and is best addressed on a case-by-case basis.

The final rule includes a definition that incorporates some of the concepts in the USSG and the general principle that cooperation must be both timely and thorough. It is intended to make clear that cooperation should include all information requested as well as all pertinent information known by the contractor necessary to complete the investigation, whether the information helps or hurts the contractor. Contractors are expected to make their employees available for Government investigators and auditors investigating contract fraud and corruption and respond in a timely and complete manner to Government requests for documents and other information required to conduct an investigation of contract fraud and corruption.

Responding to concerns expressed by the respondents, the Councils have incorporated the following definition into the final rule at 52.203–13(a):

''*Full cooperation*''—

(1) Means disclosure to the Government of the information sufficient for law enforcement to identify the nature and extent of the offense and the individuals responsible for the conduct. It includes providing timely and complete response to Government auditors' and investigators' requests for documents and access to employees with information;

(2) Does not foreclose any contractor rights arising in law, the FAR, or the terms of the contract. It does not require—

(i) A contractor to waive its attorney-client privilege or the protections afforded by the attorney work product doctrine; or

(ii) Any officer, director, owner, or employee of the contractor, including a sole proprietor, to waive his or her attorney client privilege or Fifth Amendment rights; and

(3) Does not restrict a contractor from—

(i) Conducting an internal investigation; or

(ii) Defending a proceeding or dispute arising under the contract or related to a potential or disclosed violation.

5. Suspension/Debarment

a. New Cause for Suspension or Debarment

Various respondents expressed concern that the proposed rule establishes failure to timely disclose a violation as a new cause for suspension or debarment, rather than suspension or debarment just for the underlying violation.

Response: The requirement for timely disclosure could in some circumstances be considered a new cause for suspension or debarment. However, the question of timely disclosure will not come up unless the Government independently discovers that there has been a significant overpayment, a violation of the civil FCA, or a violation of Federal criminal law to be disclosed, that the Contractor knew about and elected to ignore. It is unlikely that any contractor would be suspended or debarred absent the determination that a violation had actually occurred. Present responsibility is the ultimate basis of suspension or debarment.

b. Unnecessary and Not Good Policy

Many respondents criticized the additional suspension and debarment coverage in the proposed rule as

unnecessary and redundant to existing regulations that—

• Provide strong incentives for contractors to voluntarily disclose criminal behavior;

• Require a prospective contractor to demonstrate a satisfactory record of integrity and business ethics; and

• Provide a ''panoply of methods for prosecuting and eliminating those companies that fail to abide by the highest ethical and legal standards.''

One respondent stated that the proposed suspension and debarment for ''violation of Federal criminal law'' simply repeats much of what is contained in FAR 9.406–2 and 9.407–2. Another respondent considered the suspension and debarment regulations punitive.

Response: As addressed in the preceding paragraph, the added causes for suspension/debarment add the requirement to timely disclose the violation and are not duplicative of the violation itself as a cause for suspension/debarment.

The suspension and debarment policies and standards are not punitive. The purpose of suspension and debarment is to ensure that the Government does business only with responsible contractors, not to punish. This final rule continues to embrace the responsibility standard.

c. Mitigating Factors

Several respondents were concerned whether the proposed rule maintains the current scheme of ten mitigating factors at FAR 9.406–1(a) or renders it meaningless by establishing failure to disclose itself as a cause for debarment (thus preventing ''voluntary'' disclosure).

Response: The mitigating factors currently at FAR 9.406–1(a) will continue to be used, and a contractor's timely disclosure to the Government will continue to be a mitigating factor. As stated in the response in paragraph B.3.a.vi. ''Incentives'', above, the incentives in the FAR and the USSG are not limited to ''voluntary'' disclosures but to ''disclosures.''

Even if disclosure is ''mandatory,'' incentives will still be offered to promote compliance. The Councils do not recommend any revision as a result of these comments.

d. Undefined Terms

Many respondents expressed concern that terms such as ''knowing,'' ''timely'' ''reasonable grounds to believe,'' and ''overpayment'' are undefined and will thus put contractors at risk. One Government respondent suggested adding ''knew, should have known, or'' to ''had reasonable grounds to believe.''

Response: See responses under paragraph B.3.b.''Vagueness of rule.'' for discussions of ''timely,'' and ''reasonable grounds to believe.''

With regard to the term ''knowing failure to disclose'' the ''knowing'' refers to the failure to disclose. ''Knowing failure to disclose'' was added in the proposed rule to the causes for debarment at FAR 9.406–2(b)(1)(vi) and the causes for suspension at FAR 9.407–2(a)(8). Requiring a ''knowledge'' element to the cause for action actually provides more protection for contractors. The Councils do not agree with adding ''or should have known.'' The principals are only required to disclose what they know. Further, using the standard of ''credible evidence'' rather than ''reasonable grounds to believe'' will help clarify ''knowing'' (See response at ''Vagueness of rule'' at paragraph B.3.b.i., ''Reasonable grounds to believe'').

The term ''overpayment'' is described in a number of FAR clauses and provisions and does not require a definition with respect to suspension and debarment. For further discussion of overpayments, see response at ''Suspension and Debarment'', paragraph B.5.f. ''Limit or abandon suspension/debarment for failure to disclose overpayment''.

e. Who has knowledge?

One respondent stated that a contractor should be suspended or debarred for failing to disclose violations of Federal criminal law only if a ''principal'' of the company (as defined in the proposed contract clause) has knowledge of the crime. Failure to disclose crime should not be a basis for suspension or debarment if lower-level employees, who are not managers or supervisors, commit a crime and conceal the crime from the contractor's supervisory-level personnel.

Response: Paragraph (a)(2) of the clause at FAR 52.209–5 defines ''principals'' to mean ''officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (*e.g.* , general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions)''. The Councils agree with the respondent and have revised 3.1003(a)(2), 9.406–2(b)(1)(vi), and 9.407–2(a)(8) to make disclosure mandatory when a principal of the company has knowledge. The Councils have also added the definition of a principal at FAR 2.101 because it now applies to more than a single FAR part, and revised both definitions to be singular rather than plural.

The Councils note that this definition should be interpreted broadly, and could include compliance officers or directors of internal audit, as well as other positions of responsibility.

f. Limit or Abandon Suspension/Debarment for Failure To Disclose Overpayment

One respondent stated that the proposed ability to suspend or debar for failure to disclose an ''overpayment'' on a Government contract may create operational difficulties because contracts are subject to reconciliation processes with payments audited and adjusted over time. Likewise, another respondent stated that singling out routine contract payment issues, which are daily events, with errors on both sides, is simply unworkable. The respondent cites a situation where a defense contractor did disclose an overpayment to the payment office, only to be told that it was wrong, yet was later made the subject of a *qui tam* action. Another respondent likewise objected to making reporting of overpayments grounds for suspension or debarment rather than a matter of contract administration. The respondent stated that the proposed rule does not connect overpayments to the criminal law violations upon which the rest of the proposed rule is focused.

One respondent recommended that the FAR Council should abandon the proposed changes that would make failure to disclose an ''overpayment'' a new cause for suspension or debarment because a number of current FAR clauses already require the contractor to disclose specific types of overpayments, *e.g.* , 52.232–25, 52.232–26, 52.232–27, and 52.212–4(i)(5). These clauses treat such overpayments as a matter of contract administration and do not treat them as a matter of possible fraud and a basis for suspension or debarment. In addition, the Part 9 provisions should state explicitly that the cause for suspension or debarment is for violation of the requirements in FAR 52.232–25, 52.232–26, 52.232–27, and 52.212–4(i)(5). The respondent noted that the proposed rule did not demonstrate that the present FAR provisions requiring the disclosure of overpayments are ineffective.

On the other hand, another respondent stated that contractors currently have no obligation to report overpayment.

One respondent was more specifically concerned that overpayments can result from indirect rate variances or similar credits that can occur years after

contract performance and that can put the contractor in an over-billed situation. The severe sanctions that could inure to contractors so situated seem patently unfair. The respondent suggested either excluding rate variances or applying the section only to payments made during or immediately following contract performance.

Another respondent was concerned that this ethics rule creates potential inconsistency in the treatment of overpayments with the existing regulatory provisions of the FAR, and recommends deletion of the issue of ''overpayment'' as a basis for suspension and debarment.

DoJ suggested some answers to these concerns. DoJ considers that a duty to disclose an overpayment is just as important as the disclosure of criminal violations, and the requirement to disclose both will save the contractor from having to decide whether a criminal violation has in fact occurred in the case of an overpayment. However, DoJ concedes that a materiality requirement is appropriate to limit the scope of the requirement to disclose overpayments.

Response: The Councils dispute the allegation that ''contractors currently have no obligation to report overpayments'' and refers the respondent to the payment clauses at FAR 52.232–25, 52.232–26, 52.232–27, and 52.212–4(i)(5). Although other clauses already require reporting of overpayment, this inclusion of the requirement in Subpart 9.4 to disclose significant overpayments is necessary to make it clear that, if a contractor does not meet this condition of the contract, it can be subject to suspension or debarment.

The Councils agree with the suggestion by the DoJ that it is appropriate to limit the application of suspension or debarment to cases in which the unreported overpayment is significant. This will resolve some of the respondents' concerns over routine contract payment issues. The Councils have revised the final rule to address only significant overpayments, which implies more than just dollar value and depends on the circumstances of the overpayment as well as the amount. Since contractors are required by the Payment clauses to report and return overpayments of any amount, it is within the discretion of the suspension and debarment official to determine whether an overpayment is significant and whether suspension or debarment would be the appropriate outcome for failure to report such overpayment.

Rate variances do not need to be specifically excluded by the case because this issue is already taken care of in Part 32 and the Payment clauses. Rate variances are not considered overpayments until the rates are determined. The suggestion to apply the section only to payments made during or immediately following contract performance would not necessarily exempt rate variances, depending on when the rates are determined.

Further, the Councils decided to exclude knowing failure to report overpayments that result from contract financing payments, as defined in FAR 32.001, as grounds for suspension or debarment. Even though such overpayments must be reported and returned under the Payment clauses, these ongoing payments that are not the final payment on a contract are often based on estimates, and are subject to correction as the contract progresses. This rule is aimed at the type of overpayment that the contractor knows will result in unjust enrichment, and yet fails to disclose it.

The Councils have ensured that there is no overlap or inconsistency between this final rule and the current FAR requirements relating to overpayment, as well as the Contract Debt case published as part of Federal Acquisition Circular 2005–27 on September 17, 2008 (73 FR 53997).

g. Blacklisting

One respondent had a different concern, that the proposed changes in Part 42 with regard to past performance would allow ''blacklisting'' of contractors through consideration of ''integrity and business ethics'' in the past performance evaluation without due process protections. The respondent stated that the suspension and debarment procedures are the proper means to address responsibility issues.

Response: A contractor's satisfactory record of integrity and business ethics has long been one of the required elements for determining that a prospective contractor is responsible (see FAR 9.104–1(d)). The rules for assessing responsibility at FAR Subpart 9.1 provide for sufficient standards to ensure that offerors are treated fairly. FAR 15.306(b)(1) and (d)(3), and 42.1503(b) give the contractor the opportunity to comment on adverse past performance. The Councils do not recommend any change as a result of this comment.

h. Amendment of the Civil FCA

One respondent believed that the proposed cause for suspension/debarment language effectively amends the civil FCA. The respondent objected to changing contractors' obligations regarding overpayments without using the legislative procedure.

Response: The Councils disagree that the rule intended to, or did, amend the civil FCA outside the legislative process. The civil FCA provides a legal tool to counteract fraudulent billings turned in to the Federal Government by encouraging ''whistleblowers'' who are not affiliated with the Government to file actions against Federal contractors, claiming fraud against the Government. It also provides incentives to contractors to self-disclose. This does not preclude the Government from imposing an obligation on Federal contractors to themselves disclose to the Government if instances of overpayment are known to the company principals, and to hold them liable for knowing failure to disclose such an overpayment. This rule provides another tool to determine present responsibility of Government contractors.

FAR Subpart 9.4 provides debarment/suspension as a possible consequence for conviction of or civil judgment for commission of fraud or a variety of criminal offenses, although those statutes may already provide criminal or civil penalties for violation thereof. For example, the Sherman Act (15 U.S.C. 1–7) provides statutory penalties, including fines and imprisonment, for violation of the antitrust provisions of the statute. It is not inconsistent with the statute, nor does it require legislative amendment to include in the FAR that violation of the Federal statutes in submission of an offer is cause for debarment or suspension.

i. Technical Corrections

The Councils moved FAR 3.1002(c) to 3.1003(a)(2), because it presents a requirement rather than just policy guidance. In addition, the term ''Mandatory'' was removed from the phrase ''Mandatory requirements'' at 3.1003, because it is redundant. The title of paragraph (a)(1) of FAR 3.1003 has been amplified to indicate that this paragraph is describing contractor requirements.

6. Extend to Violation of Civil False Claims Act

a. Support Application to Disclosure of Violations of the Civil FCA

The Department of Justice, Civil Division, which is responsible for the enforcement of the civil FCA, fully supports the extension of the proposed rule to require that contractors report violations of the civil FCA, 31 U.S.C. 3729 *et seq.*, and to provide that the knowing failure to timely disclose such violations may be grounds for

suspension or debarment. Various respondents, including agency OIGs, express support for these provisions.

Response: Concur.

b. Same Issues as Raised With Regard to Other Mandatory Disclosures

Numerous respondents suggested that certain of their objections to the original proposal to require disclosure of criminal violations and to make a knowing failure to timely disclose such violations grounds for suspension or debarment, also apply to an expanded requirement that contractors disclose civil FCA violations. For example, some commented that disclosure should not be required because the conduct constituting violation of federal criminal law or the civil FCA is potentially broad and subject to varying interpretations by the Government, contractors and courts (and by relators in civil *qui tam* suits); that the requirement that violations be ''timely'' disclosed upon ''reasonable grounds to believe'' a violation has occurred are subject to varying interpretations as to when and under what circumstances a violation must be disclosed; that there is no rational basis for the proposed rule; that the rule would impose an unreasonable burden on contractors; and, that knowing failure to timely disclose should not be cause for suspension or debarment.

Response: These areas of concern common to both criminal and civil violations are addressed in other sections of this report. As discussed more fully elsewhere, the Councils have replaced the ''reasonable grounds to believe'' standard of the proposed rule with a ''credible evidence'' standard in the final rule, and to specify that the violation must have a nexus to contract award, performance or close-out, and to clarify that it is the knowledge of the principal that triggers the suspension and debarment cause. See responses under ''Vagueness of rule'' at paragraph B.3.b.i. (Reasonable grounds to believe); B.3.b.ii.(Timely disclosure); B.3.b.iii. (Criminal violation in connection with contract award or performance); and B.3.b.iv. (Level of employee with knowledge).

c. Issues Particular to the Civil FCA

i. Difficult to determine if violation has occurred. Several respondents urged that contractors should not be required to disclose violations of the civil FCA or be subject to suspension or debarment for a knowing failure to do so on a timely basis because, they suggest, the potential misconduct covered by the Act is broad, and the application of the statute raises many difficult factual and legal issues that the Government, contractors, relators and courts interpret in various ways. For example, one respondent argues that the contractor and the Government are not always aligned on whether a violation of the civil FCA has occurred, and suggests that it is impractical to assume that an average contractor employee will know definitively when a violation of the civil FCA has occurred. Several respondents observe that that there are many difficult legal and factual issues that arise in civil FCA matters, such as whether a submission constitutes a ''claim'', whether a statement is ''false,'' and whether the person making the statement or submitting the claim acted with the requisite knowledge. Another respondent argues the courts are in conflict over what conduct constitutes a violation of the civil FCA. Another respondent considers it unfair to require contractors to make civil FCA liability determinations given conflicting judicial interpretations of the civil FCA and the contractor's inability to access relevant facts. This respondent argues that certain Federal appellate courts and the United States Supreme Court have read a materiality requirement into the civil FCA even though that element is not stated explicitly in the text. One respondent cites a split in the circuits regarding whether an entity that is subject to complex regulatory requirements can be held liable under the civil FCA when the entity bases its conduct on a reasonable interpretation of an ambiguous statute or regulation. Another respondent states that whereas federal crimes are fairly well-defined, novel and aggressive interpretations of the civil FCA have created an environment in which many claims of breach of a contract might be construed as civil FCA violations.

Based on the premise that violations of the civil FCA are difficult to define, several respondents concluded that contractors will be subject to suspension and debarment if the contractor misinterprets the circumstances and does not report a violation, even if there exists an honest disagreement about whether a violation of the civil FCA has occurred.

Response: The Councils do not agree that the requirements of the civil FCA cannot be reasonably ascertained and understood by contractors, and expects that contractors doing business with the Government are taking appropriate steps to ensure their compliance with that statute and all other applicable laws. The most recent amendments to the statute were made in 1986, and a significant body of case law interpreting the statute, and the 1986 amendments in particular, has developed in that time period. These cases interpret the various elements of a civil FCA violation, including the definition of a claim, falsity, knowledge, and damages.

Although the Councils recognize that some issues concerning the proper application of the civil FCA remain unsettled and subject to further judicial interpretation, this is not unique to the civil FCA.

Moreover, the disclosure requirement applies only where the contractor has ''credible evidence'' that a violation of the civil FCA has occurred. The contractor is subject to suspension and debarment for failure to timely disclose the violation only where the contractor does so knowingly. Genuine disputes over the proper application of the civil FCA may be considered in evaluating whether the contractor knowingly failed to disclose a violation of the civil FCA.

In this regard, the Councils note that the mere filing of a *qui tam* action under the civil FCA is not sufficient to establish a violation under the statute, nor does it represent, standing alone, credible evidence of a violation. Similarly, the decision by the Government to decline intervention in a *qui tam* action is not dispositive of whether the civil FCA has been violated, nor conclusive of whether the contractor has credible evidence of a violation of the civil FCA.

ii. Broad scope of civil FCA. Several respondents suggested that requiring contractors to disclose violations of the civil FCA significantly expands the situations in which disclosure must be considered, and notes that the civil FCA can be violated even in situations where the Government suffers no financial loss. One respondent states that the civil FCA encompasses an ''almost limitless universe of activities.''

Response: The Councils do not agree that requiring disclosure of civil FCA violations will significantly broaden the situations where disclosure must be considered. Concerning the suggested breadth of the civil FCA, please see response to ''Issues particular to the civil FCA'', at paragraph B.6.c.i. ''Difficult to determine if violation has occurred''. The first proposed rule required contractors to disclose significant overpayments and violations of criminal law in connection with a Government contract or subcontract awarded thereunder, and the addition of the civil FCA is a natural extension of the rule. When a claim or payment comes under review, it often is not known at the outset of the investigation whether the matter is an overpayment, or a civil or criminal violation. In many cases, the same investigation must be done to determine the nature of the

conduct at issue. The same fraud may be actionable under the civil FCA or its criminal analogs, and require proof of the same general elements. *See, e.g.*, 18 U.S.C. 287 (criminal False Claims Act); 18 U.S.C. 1001 (false statements).

Moreover, the fact that a course of conduct can violate the civil FCA even if the Government does not suffer a financial loss does not mean that disclosure is not relevant to the contractor's present responsibility. For example, the Government may avoid a financial loss because a contracting officer alertly catches and declines to pay a false or fraudulent claim, or perhaps because the false claim is disclosed by the contractor.

iii. Mitigation in civil FCA for voluntary disclosure. One respondent argues that there is no need to make failure to timely disclose a civil violation of the civil FCA a basis for suspension and debarment because the civil FCA already provides that damages may be reduced from trebles to doubles where the contractor discloses a violation to the United States. Another respondent suggests that the proposed FAR rule would convert these otherwise voluntary disclosures into mandatory disclosures, thereby preventing contractors from benefiting from the damages reduction provision of the civil FCA. One respondent requests that the final rule clarify that any mandatory reporting obligation is not intended to and does not prevent a contractor from seeking, and the Government from providing, reduced damages as a result of a disclosure made in compliance with the new contract provision.

Response: The Councils do not agree that the reduced damages available to contractors who disclose violations of the civil FCA in accordance with that Act obviates the need for the proposed amendment to make a failure to timely disclose a violation the basis for suspension or debarment. These provisions address two separate Governmental interests. The damages provisions of the civil FCA address the Government's ability to recoup its loss as a result of a violation, and recognize that timely disclosure is an important means for mitigating that loss. Suspension and debarment is concerned with the contractor's present responsibility. Timely disclosure of violations of the civil FCA is an important indicator of the contractor's present responsibility.

The mitigating provisions of the civil FCA apply to any disclosure that meets the requirements set forth in 31 U.S.C. 3729(a)(A). There is nothing in the FAR rule that would preclude a contractor from meeting the actual requirements of the reduced damages provision of the civil FCA. (See response at paragraphs B.3.a.vi. and B.5.c. discussing the mitigating factors in the USSG and in the FAR.) In its comments to the proposed rule, the Civil Division of DOJ, which enforces the civil FCA for the United States, noted that a contractor that meets both the disclosure requirements of the FAR and the civil FCA ''would receive the dual benefit of qualifying to seek reduced damages under the civil FCA and avoiding the potential for suspension and debarment under the FAR.''

iv. Proposed amendments to the civil FCA. Several respondents suggest that a contractor making a mandatory disclosure of a violation of the federal civil FCA risks prompting a potential relator to file a *qui tam* suit based on the disclosure, and note that the public disclosure bar under existing law likely would not bar such a suit. These respondents further suggest that this risk is increased if proposed amendments to the civil FCA (S.2041 and H.4854) are enacted because they would eliminate the public disclosure bar as a jurisdictional defense to a *qui tam* suit.

Response: The Councils recognize that mandatory disclosure of a violation of the civil FCA presents a risk that a *qui tam* action will follow. This risk is not unique for disclosures of civil FCA violations; the same risk arises from disclosures of overpayments and violations of criminal law. Furthermore, the underlying violation itself presents a risk of a *qui tam* action. Timely disclosure of a knowing violation offers the contractor an opportunity to demonstrate its present responsibility to avoid suspension or debarment, and to obtain a reduction in damages under the civil FCA.

v. Healthcare and banking. Several respondents disagreed with the view expressed by DOJ that the civil FCA reporting requirement imposes on Government contractors the same disclosure standards as those required of the healthcare and banking industries, and that no law requires disclosure of a civil FCA violation.

Response: See response, in paragraph B.3.a.iii.*a.* under ''Mandatory disclosure to the OIG'', ''More far-reaching''.

vi. Inherently governmental. One respondent objects that requiring contractors to disclose violations of the civil FCA to the Government would force contractors to interpret and enforce Federal law, which epitomizes an inherently governmental function.

Response: The Councils disagree that the mandatory disclosure provisions result in a transfer of an inherently governmental function to contractors. As noted in response B.6.c.i. above, individuals and entities contracting with the Government are subject to the civil FCA, and the Government expects that its contractors will take appropriate steps to ensure their compliance with all applicable laws. Compliance necessarily requires that contractors interpret the law as it may apply to their own circumstances and conduct, and this obligation is no different whether the law is civil or criminal. The Government will continue to exercise its independent judgment as to the proper interpretation of the civil FCA, to enforce the civil FCA consistent with applicable law, and to pursue violations of that law where appropriate, irrespective of whether those violations are brought to its attention by a contractor's disclosure or otherwise.

vii. Technical correction. One respondent is concerned that with addition of disclosure of violations of the False Claims Act, it is not entirely clear whether the limiting clause ''in connection with the award or performance of this contract or any subcontract thereunder'' applies to reporting both violations of Federal criminal law and violations of the civil FCA.

Response: Concur. The Councils have modified the rule accordingly.

7. Application to Acquisition of Commercial Items

a. Support Application to Acquisition of Commercial Items

An agency OIG, in commenting on the first proposed rule, believed that the responsibility of the contractor to report potential violations of criminal law or safety issues related to Government contracts or subcontracts should not be based on contract type and should not exclude commercial contracts from the reporting requirement.

In response to the question on the expansion of the second proposed rule to apply to commercial items, various respondents, including many agency OIGs, support application to contracts for the acquisition of commercial items.

Response: Concur.

b. Do Not Support Application to Acquisition of Commercial Items

Several respondents state that the proposed rule is inconsistent with Public Law 103–355 and FAR Part 12.

Another respondent is concerned that application of the proposed rule to commercial acquisitions will be difficult for educational institutions to implement.

Another respondent states that DoJ fails to show any deference to OFPP

with respect to commercial item policy, asserting without any rationale or elaboration that there would be no reason to exclude so-called commercial item contracts. This respondent states that the rule cannot be applied to commercial items without specific authorization by Executive Order or statute.

One respondent believes that applying Government-unique clauses to commercial suppliers will drive them away from the Government marketplace. Since this respondent recognizes that this is now required by statute, they will continue to seek a repeal of the statute.

Another respondent recommends against requiring commercial item contractors to develop new, Government-only ethics standards that result in a company having two standards of conduct, one for Government business and one for everything else.

Response: The disclosure requirements of the new statute specifically apply to commercial items. Furthermore, the statute includes the words ''pursuant to FAR Case 2007–006 or any follow-on FAR case'' which the Councils interpret as covering the inclusion of the civil FCA as addressed in the second proposed rule.

c. Application to Commercial Subcontracts

One respondent questions whether application of the proposed rule to the business practices of a commercial vendor that has no direct contractual relationship with the Federal Government has any relevance to assuring proper stewardship of Federal funds.

One respondent is concerned that without a more distinct definition of ''subcontractor,'' the flowdown obligation may be applied more broadly than necessary. The respondent requests additional guidance in order to distinguish actual subcontractors from entities that may be contracted to provide collateral services to the commercial contractor (*e.g.*, service vendors, licensors, corporate subsidiaries).

Further, another respondent states that revision to FAR Subpart 44.4 or FAR clauses 52.212–4 or 52.212–5 and clause 52.244–6 would be necessary before this requirement can be flowed down to commercial item subcontractors, but because the proposed rule has neglected to specify changes, there is no proposed authorization to revise those clauses in the final rule.

Response: ''Subcontract'' and ''subcontractor'' are defined at FAR 44.101. To clarify the meaning in this context, the Councils have borrowed from those definitions for use in the text at 3.1001 and in the clause at FAR 52.203–13.

The Councils are authorized to make any revisions to Subpart 44.4, Part 12 and Part 44, necessary to conform changes in the final rule, as long as changes in the final rule are reasonably foreseeable from either the proposed rule text or the discussions in the preamble. This constitutes adequate notice to the public. Both the text and preamble of the May 16, 2008, proposed rule were specific that the rule would apply to subcontracts. The Councils have made appropriate conforming changes to 52.212–5 and 52.244–6.

d. Other Concerns

One respondent questions whether the phrase ''if 52.212–4 appears in this contract'' (52.203–13(c)) is another way of saying it is a commercial item contract.

Response: Yes, inclusion of clause 52.212–4 in the prime contract would indicate that it is a contract for the acquisition of commercial items. However, now that the final rule requires flow down to commercial subcontracts, this phrase is inadequate for indicating a subcontract for commercial items, and has been revised accordingly.

e. Comments on the First Proposed Rule That Are No Longer Applicable

One respondent was concerned that the opportunity for substantial confusion exists with the rule and recommends additional guidance on how the rule impacts companies selling commercial items under FAR Part 8 acquisitions.

Another respondent was concerned that the proposed language at 3.1004 ''awarded under FAR Part 12'' is likely to be misunderstood as applying only when the policies of FAR Part 12 are used exclusively and the procedures in Parts 13, 14, and 15 are not used.

Another respondent was concerned that the proposed rule does not properly address the exemption for commercial item vendors.

One respondent was concerned that the proposed rule does not justify imposing the new cause for suspension or debarment based on failure to disclose a ''violation'', and that will also place restrictions on commercial contractors that are not required by law and not consistent with the commercial market place.

Response: These comments are no longer applicable because the statute now requires application of most of this rule to commercial item contracts.

8. Application to Contracts To Be Performed Outside the United States

a. Support Application Outside the United States

Four respondents to the first proposed rule questioned the exceptions for overseas contacts.

- DoJ disagreed with excluding contracts performed entirely outside the United States from the requirements of the rule. The respondent indicates that the United States is still party to such contracts and potentially a victim when overpayments are made or when fraud occurs in connection with the contacts.
- One respondent was concerned that the rule exempts contracts performed overseas without providing an explanation as to why a basic policy of a code of ethics and business conduct should not apply overseas.
- An agency OIG believed that the responsibility of the contractor to report potential violations of criminal law or safety issues related to Government contracts or subcontracts should not be based on contract type and should not exclude contracts performed outside the United States from the reporting requirements.
- Another agency OIG believed that it is counterproductive to exclude contracts performed entirely outside the United States because the United States is still party to such contracts and may be victimized when overpayments are made or fraud occurs in connection with those contracts. The respondent also argues the contracts require greater vigilance because they are performed overseas where U.S. resources and remedies are more limited; and that the inclusion would reduce the vulnerabilities that often plague overseas programs and increase the effectiveness of those programs.

In response to the proposed expansion overseas in the second proposed rule, various respondents, including several agency OIGs, support making the requirements of this rule applicable to contracts and subcontracts performed outside the United States.

Response: Concur.

b. Do Not Support Application Outside the United States

One respondent raised the concern that if any part of the work is performed outside the United States, labor and privacy laws in Europe would prohibit mandatory reporting by employees.

Another respondent is concerned that extension of the requirements to contracts and subcontracts performed

outside the U.S. will likely have a significant and negative effect on academic institutions' ability to engage international partners. It is inappropriate and impractical to expect our international partners to do business in the same way as U.S. organizations. Many foreign academic institutions are instrumentalities of foreign governments and are subject to their own laws and regulations. Without flexibility, it will be impossible to pursue the international research and education

One respondent also believes that it is unreasonable and impractical to expect foreign firms to understand and be able to comply with the unique procedural requirements the U.S. imposes on its contractors. This respondent recognizes that this is now required by statute and it will seek a repeal of the statute.

Response: The disclosure requirements of the new statute specifically apply to acquisitions to be performed outside the United States. Furthermore, the statute includes the words ''pursuant to FAR Case 2007–006 * * * or any follow-on FAR case'' which the Councils interpret as covering the inclusion of the civil FCA as addressed in the second proposed rule.

9. Other Applicability Issues

a. Educational Institutions

i. Exempt educational and research institutions. One respondent requested that educational and research institutions be granted the same exemption afforded small business by making the requirement for a formal training and/or awareness program and internal control systems inapplicable to such institutions.

Response: By passing the ''Close the Contractor Fraud Loophole Act,'' Congress made clear its preference for fewer, rather than more exemptions. The requirements at 3.1002(b) are that the ethics and compliance training program be suitable to the size of the entity and extent of its involvement in Government contracting. Further, this regulation applies only to contracts using appropriated funds, not to grants.

ii. Imposition of procurement requirements on grant recipients. One respondent stated that OMB regulation 2 CFR 215.40 forbids agencies to impose procurement requirements on grant recipients unless required by statute or Executive order or approved by OMB.

Response: This rule is not imposing any requirements on grant recipients. The FAR does not apply to contracts awarded using grant money. Federal Government grant recipients who are also Federal Government contractors must comply with both the grant regulations and the FAR, as applicable.

b. Subcontractors

Various responses were received on the obligations imposed by this rule between contractors and subcontractors and the flow down of this rule to subcontractors.

Response: The Councils note that the same rationale that supports the application of the rule to prime contractors supports the application to subcontractors. The same reasonable efforts the contractor may take to exclude from its organizational structure principals whom due diligence would have exposed as engaging in illegal acts are the same reasonable efforts the contractor should take in selecting its subcontractors. Subcontractors should also use those same reasonable efforts in employment and subcontracting efforts.

i. Obligation to report violations by subcontractors. According to several respondents, prime contractors should not be responsible for oversight of their subcontractors and should not be subject to debarment for failure of a subcontractor to meet the requirement of the rule. The respondents were concerned that the rule renders prime contractors police for their subcontractors which respondents consider unreasonable and burdensome. One respondent was also concerned that rule creates a contractual obligation on the part of the contractor to ensure that its subcontractors perform as required by the rule. Another respondent stated that the rule fails to define the obligation of the contractor to police its subcontractors with regard to the required compliance program and integrity reporting. It is unclear what degree of due diligence the Government expects of the contractor.

Response: There is no requirement for the contractor to review or approve its subcontractors' ethics codes or internal control systems. Verification of the existence of such code and program can be part of the standard oversight that a contractor exercises over its subcontractors. The prime contractor is subject to debarment only if it fails to disclose known violations by the subcontractor. Therefore, a change to the rule is not necessary.

ii. Disclosure through the prime contractor. One respondent was concerned that the rule mandates that the disclosures go directly to the Government and not through the prime contractor. DoJ was concerned that some subcontractors may not be comfortable making disclosure through the prime contractor and suggested that a mechanism through which a subcontractor makes a disclosure be addressed in the final rule.

Response: The clause flow down in paragraph (d)(2) states that in altering the clause to identify the appropriate parties, all disclosures of violations of the civil FCA or of Federal criminal law shall be directed to the agency OIG, with a copy to the contracting officer. The clause does not require disclosure through the prime contractor.

iii. Liability for erroneous disclosure. One respondent was concerned that the rule creates a potential significant liability for the contractor if disclosures concerning subcontractors turn out to be in error. The respondent requested the Councils to consider whether damages assessed against contractors for erroneous reports would be allowable costs. Also, the respondent was concerned that the rule is unclear about the disclosure of criminal violations by subcontractors, and suggests that the Councils revise the rule to make the disclosure requirements for the contractor and the subcontractor parallel.

Response: The Councils revised the rule to require the contractor to disclose credible evidence of a violation of Federal criminal law in connection with the contract or any subcontract under the contract. This revision provides to the contractor sufficient opportunity to take reasonable steps to determine the credibility of any possible disclosure prior to disclosing it to the agency Inspector General and contracting officer. The potential for erroneous disclosure is minimized by requiring the contractor to disclose only credible evidence of violations, thereby reducing the contractor's potential liability for damages associated with erroneously disclosing alleged violations which are not substantiated.

c. Small Businesses (See Also Paragraph 11. ''Regulatory Flexibility Act Concerns'', for Comments on Initial Regulatory Flexibility Analysis)

i. Support level of applicability to small businesses. An agency OIG supported the application of the basic requirements of the rule to small business because the rule avoids imposing unnecessary burdens on small businesses by creating expensive paperwork requirements. Likewise, another agency OIG considered the exemption for small business contractors (from the requirements for a formal internal control system) reasonable. Another agency OIG also indicated that undesirable results for small business which could have resulted from initial drafts of the rule have been mediated by this rule.

Response: Concur.

ii. Overly burdensome on small business: One respondent believed that the rule is an overly burdensome and unrealistic policing requirement that imposes significant new cost requirements and is particularly burdensome for small businesses; effectively precluding such businesses from competing for prime contract work or as a high-tier subcontractor.

• *Response:* Although the rule may have a significant economic impact on a substantial number of small entities with respect to the disclosure requirement, the rule is structured to minimize its impact on small business concerns by making the requirement for formal training programs and internal control systems inapplicable to small businesses, and limiting the disclosure requirement of violations of Federal criminal law to those violations involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code, although the rule did add the reporting of violations of the False Claims Act. The Councils do not believe that a change to the rule is necessary.

d. Dollar Threshold or Minimum 120 Day Performance Period

i. Recommend no threshold and no minimum performance period. One agency OIG commented on the rule's threshold of $5 million and 120-day performance period. The agency OIG believed that the application of the rule should not be determined on the basis of the dollar value or the period of performance of the contract. The respondent was concerned that, at times, contracting officers have awarded smaller dollar value contracts or modifications instead of one large dollar contract to circumvent various thresholds that trigger requirements. The respondent believed that the public and members of Congress have similar expectations of all contractors no matter the contract value or type.

Response: The Close the Contractor Fraud Loophole Act (Pub. L. 110–252, Section 6103) now defines a covered contract for application of this regulation as any contract in an amount greater than $5 million and more than 120 days in duration. The Councils also note that, regardless of whether the clause is included in the contract, the suspension and debarment provisions in Subpart 9.4 apply to all contractors, regardless of contract value or duration.

ii. Applicability of thresholds to Federal Supply Schedule (FSS) contracts and Blanket Purchase Agreements (BPA). One respondent requests explanation of the applicability of the thresholds to FSS contracts. The respondent does not believe that FAR 1.108(c) adequately clarifies the issue. Are the thresholds based on each individual order?

Response: According to FAR 1.108(c), unless otherwise specified, if the action establishes a maximum quantity of supplies or services to be acquired, the final anticipated dollar value must be the highest final priced alternative to the Government, including the dollar value of all options. That is, if it is anticipated that the dollar value of orders on an FSS contract will exceed $5 million, then this clause is included in the basic contract against which orders are placed.

e. Single Government Standard Also Applicable to Grants

One respondent was concerned that multiple Federal agencies already have compliance guidelines and regulations in place, or in development, and believes the rule may be inconsistent with other Federal agency requirements. The respondent requested that a single Federal Government-wide standard be created to foster integrity and honesty that applies to both Government contracts and Federal grants.

Response: The Councils acknowledge the respondent's concern. However, this rule establishes a Government-wide standard for contractor compliance programs and integrity reporting with respect to Government contract awards. Under the rule, all Federal agencies will be required to implement the same requirements in the same manner consistent with the award of Federal contracts. However, the rule does not and is not intended to address contractor compliance programs and integrity reporting with respect to agency grant-making procedures. Given the legal differences between a grant and a contract that concern performance and termination for default, the creation of a single Government standard addressing contractor compliance programs and integrity reporting is not practical and is outside the scope of the rule.

10. Additional Recommendations

a. Defer Final Rule Until

i. More experience with 2006–007. One respondent suggested that the FAR Council evaluate experience with the final rule, before proposing changes. The FAR Council should withdraw the proposed rule in favor of allowing covered contractors to implement the November 23, 2007, final rule.

ii. Completion of the National Science and Technology Council initiative. Several respondents urged the FAR Council to defer further action on proposed FAR Case 2007–006 pending completion of the National Science and Technology Council (NSTC) initiative to develop compliance guidance for recipients of Federal research funding from all agencies across the Federal Government.

iii. Further action on related legislation that would expand the scope of the civil FCA. One respondent requests postponement until after enactment of pending legislation on the civil FCA.

iv. Public hearings. One respondent alternatively suggests additional public comment in light of the pertinent intervening legislation and public hearings.

Response: The intervening legislation requires implementation of this rule in the FAR within 180 days of enactment of Pub. L. 110–252 (by December 26, 2008). Therefore, the Councils will proceed with this rule without delay.

At the time of publishing the final rule (2006–007), the proposed rule (2007–006) under this case had already been published. The preamble of the final rule under 2006–007 stated the intent to address mandatory disclosure and full cooperation under the follow-on rule.

It is unknown when the NSTC initiative to develop compliance guidance for recipients of Federal research funding from all agencies across the Federal Government will be completed. The Councils do not agree to delay the FAR rule pending the outcome of this particular initiative. Often the regulations for grants use the FAR as a model.

b. Expand Policy and Clause to Cover Overpayments

DoJ and an agency IG commented that the drafters of the proposed rule neglected to incorporate ''knowing failure to timely disclose an overpayment'' in the first reference at 3.1002(c).

Several respondents proposed that the language in the proposed FAR clause be expanded to also include instances of overpayment. More inclusive language removes any ambiguity (and loopholes) about what should be revealed to the Government. By expanding the scope to include overpayments, contractors are no longer asked to label (or mislabel) their activity as ''criminal''. In the opinion of the respondents, the proposed rule does not match the stated objective of encouraging Government notification of fraud and overpayments.

Response: The mandatory reporting of overpayments is addressed in the

Payments clauses. However, to aid in clarity, we have added a cross reference at FAR 3.1003 to the Payment clauses and the knowing failure to timely disclose significant overpayments as a cause for suspension/debarment in FAR Subpart 9.4.

c. Create a Contractor Integrity and Business Ethics Information Section in FAR Part 42

One respondent urged the FAR Councils to create a contractor integrity and business ethics section in FAR Part 42 that would require Government officials to record and maintain integrity and business ethics information that can be shared with Government officials. Although contractor performance and responsibility are part of FAR Subpart 9.1, the respondent requests that distinctive data and information be collected on each.

Another respondent, on the other hand, is very satisfied that the rule only proposed one change to the contractor past performance information in FAR 42.1501, and properly reinforces the existing emphasis on contractor cooperation across a broad range of contract administration matters, including cooperation with investigations.

Response: The proposed rule has added a cross reference in Part 42 to promote the inclusion of business integrity in past performance. The request to collect distinctive data and information on contractor responsibility is outside the scope of this rule. The past performance databases are controlled by the agencies. (See also response to ''Suspension/Debarment'', paragraph B.5.g. ''Blacklisting'')

d. Add Safety Issues

An agency IG suggested that safety issues should be included in the mandatory disclosure requirement.

Response: Adding explicit coverage of safety issues is outside the scope of this case.

e. Protection of Contractor Disclosures

The proposed rule states at 3.1002 (Policy) that contractors should have an internal control system that facilitates timely discovery of improper conduct in connection with Government contracts. A contractor may be suspended or debarred for knowing failure to timely disclose a violation of Federal criminal law in connection with the award or performance of any Government contract performed by the contractor.

DoJ suggested that, in order to encourage contractors to submit information, the Councils may wish to recommend to agencies that the submitted information be maintained confidentially to the extent permitted by law and that any disclosure of the information under FOIA should only be made after full consideration of institutional, commercial, and personal privacy interests that could be implicated by such a disclosure. In particular, agencies should be mindful that the Trade Secrets Act operates as a prohibition on the discretionary disclosure of any information covered by Exemption 4 of the FOIA, unless disclosure is otherwise authorized by law.

Response: The Councils have added the following provision to the final rule, similar to the provision employed by the DoD Voluntary Disclosure Program (DoD Directive 5106.01, April 23, 2006) in ''XYZ'' agreements with contractors pursuant to DoD Voluntary Disclosure Program Guidance (IGD 5505.50, CIPO, April 1990) (see *http://www.dodig.mil/Inspections/vdprogram.htm*): ''The Government, to the extent permitted by law and regulation, will safeguard and treat information obtained pursuant to the contractor's disclosure as confidential where the information has been marked ''confidential'' or ''proprietary'' by the company. To the extent permitted by law and regulation, such information will not be released by the Government to the public pursuant to a Freedom of Information Act request, 5 U.S.C. section 552, *et. seq.,* without prior notification to the contractor. The Government may transfer documents provided by the contractor to any department or agency within the Executive Branch if the information relates to matters within the organization's jurisdiction.''

The addition of the above provision will provide appropriate assurance to contractors about the Government's protection afforded to disclosures.

11. Regulatory Flexibility Act concerns

a. IRFA Does Not Identify a Rational Basis for the Rule

Several respondents criticized the Initial Regulatory Flexibility Analysis (IRFA) as deficient because they believe that it does not identify a rational basis for the rule. They claim that there is no empirical or anecdotal evidence to explain why the mandatory disclosure requirement is required for the proper functioning of the procurement system.

Response: See response to ''Mandatory disclosure to the OIG'', ''Empirical support that mandatory disclosure will achieve the Councils' objective'', at paragraph B.3.a.iii.*d.*

b. The IRFA Underestimates the Number of Small Businesses Affected and the Associated Costs

Several respondents also considered that the IRFA underestimates the number of small businesses affected, as it only describes the estimated 28 small businesses which conclude that disclosure is required, rather than the larger number which will have to conduct internal investigations before concluding that disclosure is not required. One respondent pointed out the costs to run a compliance program. Another respondent pointed out that the IRFA does not ascertain the costs when a company chooses to retain outside counsel to investigate, which could range from $1 million to $20 million. The rule will cost small businesses over $1 billion a year (calculation—for each report there would be 5 internal investigations at a cost of $5 million per contractor and $2.5 million per subcontractor.)

Response: First, the IRFA estimated an impact on 45 small businesses, not just the 28 covered by the clause.

Second, an ethical company that learns that an employee may have committed a violation of Federal criminal law would not ignore this information. A company would normally investigate allegations of wrongdoing within the company as a sound business practice. If there was clearly no violation, the investigation would be short. Although the rule allows contractors time to take reasonable steps to determine that evidence of wrongdoing is credible, it does not direct contractors to carry out any particular level of internal investigation. The IRFA focused on the effort which results from this rule—disclosure to the Government—although there are other incentives outside this rule which could cause a contractor to voluntarily disclose violations to the Government, such as the U.S. Sentencing Guidelines. Although the IRFA does not include the cost of the investigation in its calculations, the FAR does not require or envision a small business paying millions of dollars for an investigation. The respondent's calculated cost estimates are not supported or credible.

The FAR did give relief for the costs of running a compliance program by leaving it to the discretion of the small business and paragraph (c) of the clause is not mandatory for small businesses.

c. Imposition of Suspension and Debarment Will Disproportionately Damage Small Businesses

One respondent stated that small businesses do not have the resources that large businesses do. They do not have the resources to institute compliance programs. They are more likely to be caught in the suspension and debarment process. They lack the leverage to negotiate agreements in lieu of debarment. Therefore, the rule's reliance on suspension and debarment as an enforcement mechanism will disproportionately damage small businesses.

Response: The Councils agree that small businesses often have fewer resources than other than small business. Nonetheless, the Councils cannot give further flexibility here. The Councils have already eliminated the requirement for the internal control system for small businesses. The Councils cannot establish a different suspension or debarment standard for small businesses.

d. Estimate of Small Businesses That Would Disclose if No Mandatory Requirement

One respondent quoted the IRFA as estimating that, in the absence of the proposed disclosure requirement, 1 percent of small business contractors that are aware of a violation would voluntarily report it. This suggests, according to the respondent, that the FAR Council believes that mandatory disclosure would lead to a 100-fold increase in the number of reported violations. The respondent states that there is no support for this estimate and no rational basis to support a claim that this disclosure requirement is needed for the effective functioning of the procurement system.

Response: The respondent has drawn an unwarranted conclusion about the estimated impact of mandatory disclosure. The estimated 1% disclosure rate in the IRFA is for small businesses that do not have the clause in their contract (*i.e.*, small dollar value or short performance period). There was no estimate in the IRFA about what percentage of this population would disclose if the clause were included. Further, any estimates about this segment of the population cannot be extrapolated to a conclusion about the effect of mandatory disclosure requirements on higher dollar value, noncommercial contracts or contracts with large businesses.

e. Recordkeeping Requirements

One respondent objected that the IRFA did not provide a full discussion of the projected recordkeeping and compliance requirements. Good business sense will require a contractor to develop and keep more records for the purpose of documenting its investigation.

Response: The Councils agree that recordkeeping would be wise, but the rule does not require recordkeeping beyond the recordkeeping that would be part of the contractor's normal business practices. Under 5 U.S.C. 601, the term ''recordkeeping requirement'' is defined as a requirement imposed by an agency on persons to maintain specified records.

f. Duplication, Overlap, or Conflict

Several respondents criticized the statement in the IRFA that the rule does not duplicate, overlap, or conflict with any other Federal rules. The respondents state that the IRFA—

- Ignored the obvious interrelationship with the civil Federal civil FCA and its *qui tam* provisions;
- Did not address the inconsistency between the proposed rule and the Federal Sentencing Guidelines; and
- Did not address that the rule is inconsistent with a voluntary disclosure being a mitigation consideration in the FAR debarment and suspension proceedings and under the civil FCA because disclosure would be mandatory rather than voluntary.

Response: Under 5 U.S.C. 601, ''rule'' is defined as meaning ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title or any other law * * *''. Codified laws are not a rule. The Sentencing Guidelines are, strictly speaking, also not a rule. However, the Councils disagree that this rule is duplicative of the civil FCA. Any inadvertent inconsistency with the Guidelines has been considered in formulating this final rule.

Regarding mitigation and voluntary disclosure, see ''Mandatory disclosure to the OIG'', ''Incentives'' at paragraph B.3.a.vi.

12. Paperwork Reduction Act (PRA)

a. Burden Underestimated

One respondent stated that the Councils' Paperwork Reduction Act analysis is inadequate. The estimates are so conservative as to be unrealistic. If it only takes 20 hours to conduct pre-disclosure review and draft a corresponding report, why does it take the Government a year to decide whether to intervene in a traditional *qui tam* case? The respondent points out that ''burden'' includes all aspects of the reporting process, including the separation of reportable events from non-reportable events.

Another respondent also considers the estimated burden of 3 hours per report woefully inadequate, considering the time needed by respondents to investigate and determine whether a civil FCA violation or criminal violation occurred.

Response: Burden includes estimated hours only for those actions which a company would not undertake in the normal course of business. The Government does not direct companies to investigate. In the normal course of business, a company that is concerned about ethical behavior will take reasonable steps to determine the credibility of allegations of misconduct within the firm. It is left to the discretion of the company what these reasonable steps may entail. The Government has added the requirement to disclose to the Government when credible evidence of misconduct is obtained, which would not necessarily otherwise occur. The estimated hours in the regulatory flexibility analysis and the paperwork burden act analysis are to cover the hours required for preparing and reviewing the disclosure to the Government when credible evidence has been obtained. The estimated hours must also be viewed as an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. However, upon further discussion with subject matter experts, the Councils have revised the estimated hours to 60 hours per response, considering particularly the hours that would be required for review within the company, prior to release to the Government.

b. Recordkeeping and Other Compliance Requirements

One respondent stated that the projected recordkeeping and compliance requirements are far more burdensome than reflected in the IRFA. The contractor must keep and maintain extensive records any time it investigates allegations or suspicions of violations. Even if a company determines that disclosure is not required, the contractor must keep records of its decision-making process in order to defend against possible future accusations of failure to disclose.

Another respondent states that time is required for 1400 covered contractors to establish systems for complying with this regulation.

Response: See the response in previous section on Regulatory Flexibility Analysis (B.11.).

c. Data and Methodology Should Be Made Part of the Rulemaking Record

Response: The public can request copies of the supporting statements.

13. Executive Order 12866

a. Significant Rule

A number of respondents are concerned that this rule is a significant rule in accordance with E.O. 12866 section 3.(f). One respondent is concerned that, by extending the rule to cover commercial acquisitions and overseas contracts, a review requirement as a ''major rule'' or a significant rule under section 3.(f)(1) may have been unintentionally triggered. Another respondent believes that the rule should have a cost-benefit analysis.

One respondent states that the addition of violations of the civil FCA as a ground for mandatory disclosure is sufficient standing alone to trigger review under Section 6(b) of E.O. 12866.

Another respondent submits that this is a significant regulatory action because it will, among other things, adversely affect in a material way a sector of the economy (Government contractors).

Several respondents also state that the second proposed rule raises important legal and policy issues, another grounds for the Office of Information and Regulatory Affairs (OIRA) to declare a rule significant under E.O. 12866, under section 3.(f)(4).

One respondent suggests that it was a Freudian slip when the FR notice for the first proposed rule stated that the first proposed rule *was* a significant regulatory action and therefore *was not* subject to review.

Response: The first proposed rule was declared to be a significant rule by OIRA. The typographical error was in the second half of the sentence, not the first. The rule was subject to review under the Executive order and was so reviewed. OIRA did not declare the second proposed rule to be a significant rule.

All rules are sent through the Office of Information and Regulatory Affairs for determination as to whether the rule is significant. OMB's Office of Information and Regulatory Affairs has determined this is a significant rule, and not a major rule.

b. Violates E.O. 12866

One respondent states that the proposed rule violates the E.O. 12866 requirement that rules be ''consistent, sensible, and understandable'' and that agencies promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need. This respondent submits that just because DoJ wants to make its job easier is not sufficient grounds for rulemaking.

Response: This rule is required by law and by compelling public need. The Councils have made every effort to make the draft final rule consistent, sensible, and understandable.

This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* applies to this final rule. The Councils prepared a Final Regulatory Flexibility Analysis (FRFA), and it is summarized as follows:

1. Statement of the need for, and objectives of, the rule.

This rule amends the Federal Acquisition Regulation to require Government contractors to—

- Establish and maintain specific internal controls to detect and prevent improper conduct in connection with the award or performance of any Government contract or subcontract; and
- Notify without delay the agency Office of the Inspector General, with a copy to the contracting officer, whenever, in connection with the award, performance, or closeout of a Government contract awarded to the contractor or a subcontract awarded thereunder, the contractor has credible evidence of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in 18 U.S.C. or a violation of the civil False Claims Act.

This case is in response to a request to the Office of Federal Procurement Policy from the Department of Justice and Public Law 110–252. Based on the requirements of Pub. L. 110–252, the rule was expanded to include the clause 52.203–13 in contracts performed overseas and contracts for the acquisition of commercial items.

The objective of the rule is to emphasize the critical importance of integrity in contracting and reduce the occurrence of improper or criminal conduct in connection with the award and performance of Federal contracts and subcontracts.

2. Summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

a. IRFA does not identify a rational basis for the rule. Several respondents criticized the Initial Regulatory Flexibility Analysis (IRFA) as deficient because they believe that it does not identify a rational basis for the rule. They claim that there is no empirical or anecdotal evidence to explain why the mandatory disclosure requirement is required for the proper functioning of the procurement system.

Response: DoJ and various OIGs provided testimony that the experience with the National Reconnaissance Organization mandatory disclosure clause has been positive. Further, enactment of the Close the Contractor Fraud Loophole Act (Pub. L. 110–252, Sec VI, Chapter 1) now mandates many of these revisions to the FAR.

b. The IRFA underestimates the number of small businesses affected and the associated costs. Some respondents considered that the IRFA underestimates the number of small businesses affected, as it only describes the estimated 28 small businesses which conclude that disclosure is required, rather than the larger number which will have to conduct internal investigations before concluding that disclosure is not required. Respondents pointed out the costs to run a compliance program and that the IRFA does not ascertain the costs when a company chooses to retain outside counsel to investigate, which could range from $1 million to $20 million. The rule will cost small businesses over $1 billion a year (calculation—for each report there would be 5 internal investigations at a cost of $5 million per contractor and $2.5 million per subcontractor).

Response: First, the IRFA estimated an impact on 45 small businesses, not just the 28 covered by the clause. Further, an *ethical* company *that* finds out an employee may have committed a violation of Federal criminal law would not ignore this. A company would normally follow up allegations of wrongdoing within the company as a sound business practice. If there was clearly no violation, the investigation would be short. Although the rule allows contractors time to take reasonable steps to determine that evidence of wrongdoing is credible, it does not direct contractors to carry out any particular level of internal investigation. The IRFA focused on the effort which results from this rule—reporting to the Government. Although there are other incentives outside this rule which could cause a contractor to voluntarily disclose violations to the Government, such as the U.S. Sentencing Guidelines. Although the IRFA does not include the cost of the investigation in its calculations, the FAR does not require or envision a small business paying millions of dollars for an investigation. The respondent's calculated cost estimates are not supported or credible.

The FAR did give relief for the costs of running a compliance program by leaving it to the discretion of the small business; paragraph (c) of the clause is not mandatory for small businesses.

c. Imposition of suspension and debarment will disproportionately damage small businesses. A respondent stated that small businesses don't have the resources that large businesses do. They do not have the resources to institute compliance programs. They are more likely to be caught in the suspension and debarment process. They lack the leverage to negotiate agreements in

lieu of debarment. Therefore, the rule's reliance on suspension and debarment as an enforcement mechanism will disproportionately damage small businesses.

Response: The Councils agree that small businesses have fewer resources than other than small businesses. Nonetheless, the Councils cannot give further flexibility here. The Councils have already eliminated the requirement for the internal control system for small businesses. The Councils cannot establish a different suspension or debarment standard for small businesses.

d. Estimate of small businesses that would report if no mandatory requirement. One respondent quoted the IRFA as estimating that, in the absence of the proposed disclosure requirement, 1% of small business contractors that are aware of a violation would voluntarily report it. This suggests, according to the respondent, that the FAR Council believes that mandatory disclosure would lead to a 100 fold increase in the number of reported violations. The respondent states that there is no support for this estimate.

Response: The respondent has drawn an unwarranted conclusion about the estimated impact of mandatory disclosure. The estimated 1% disclosure rate in the IRFA is for small businesses that do not have the clause in their contract (i.e., small dollar value or short performance period). There was no estimate in the IRFA about what percentage of this population would report if the clause were included. Further, any estimates about this segment of the population cannot be extrapolated to a conclusion about the effect of mandatory disclosure requirements on higher dollar value contracts of duration more that 120 days or contracts with large businesses. The number of small businesses affected cannot be known exactly because there is no data at this time on disclosures that will result from this rule, but the numbers represent the best estimate of subject matter experts in the Government.

e. Recordkeeping requirements. One respondent objected that the IRFA did not provide a full discussion of the projected recordkeeping and compliance requirements. Good business sense will require a contractor to develop and keep more records for the purpose of documenting its investigation.

Response: Although recordkeeping would be wise, the rule does not require it. Under 5 U.S.C. 601, the term ''recordkeeping requirement'' is defined as a requirement imposed by an agency on persons to maintain specified records.

f. Duplication, overlap, or conflict. Several respondents criticized the statement in the IRFA that the rule does not duplicate, overlap, or conflict with any other Federal rules. The respondents state that the IRFA ignores the obvious interrelationship with the Federal False Claims Act and its *qui tam* provisions and it did not address the inconsistency between the proposed rule and the Federal Sentencing Guidelines. The rule is inconsistent with a voluntary disclosure being a mitigation consideration in the FAR debarment and suspension proceedings and under the False Claims Act because disclosure would be mandatory rather than voluntary.

Response: Under 5 U.S.C. 601, ''rule'' is defined as meaning any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title. Codified laws are not a rule. The Sentencing Guidelines are, strictly speaking, also not a rule. However, the Councils disagree that this rule is duplicative of the False Claims Act and any inadvertent inconsistency with the Guidelines has been considered in formulating this final rule. The FAR, the U.S. Sentencing Guidelines, and the civil False Claims Act consider any self-disclosure to constitute a mitigating circumstance, whether voluntary or mandatory.

3. Description and estimate of the number of small entities to which the rule will apply.

The rule imposes a clause in contracts that exceed $5 million and a performance period greater than 120 days. Based on FY 2006 data collected from the Federal Procurement Data System, the Councils estimate that this clause will apply to 2700 prime contractors per year, of which 1050 companies are small business concerns.

The clause also flows down to subcontracts that exceed $5 million, and we estimate that approximately 1050 additional small business concerns will meet these conditions. We calculate the number of small business concerns that will be required by the clause to report violations of Federal criminal law with regard to a Government contract or subcontracts as follows:

1050 prime contractors + 1050 subcontractors = $2100 \times 4\% = 84$.

In addition, although there is no clause required, all contractors will be on notice that they may be suspended or debarred for failure to report known violations of Federal criminal law with regard to a Government contract or subcontract. In FY 2006 there were 144,854 small business concerns listed in FPDS–NG with unique DUNS numbers. We estimate that of the listed small business concerns, approximately 116,000 (80%) will receive contracts in a given fiscal year. Government small business experts guess that at least twice that number of small businesses (232,000) will receive subcontracts. However, the only small business concerns impacted by this cause for suspension or debarment are those that are aware of violation of Federal criminal law with regard to their Government contracts or subcontracts. Subtracting out those contracts and subcontracts covered by the clause (1050 each), we estimate this number as follows: ($114{,}950 + 230{,}950 = 345{,}900 \times 1\% = 3{,}459$). We estimate a lower percentage than used for contracts and subcontracts that contain the clause, because these are lower dollar contracts and subcontracts, including commercial contracts, and there may be less visibility into violations of Federal criminal law. Because there is no contract clause, we estimate that only 1% of those contractors/subcontractors that are aware of a violation of Federal criminal law in regard to the contract or subcontract will voluntarily report such violation to the contracting officer ($3459 \times 1\% = 34$). The estimated number of small businesses in the FRFA (119) has increased from the IRFA (45) because of the applicability of the clause to commercial contracts and contracts to be performed outside the United States and because the disclosure requirement now applies to violations of the civil False Claims Act as well as violations of Federal criminal law.

4. Description of 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.

The rule requires contractors to report to the agency office of the inspector general, with a copy to the contracting officer, violations of Federal criminal law in connection with the award or performance of any Government contract or subcontract for contracts that exceed $5 million with a contract performance period greater than 120 days, and the same criteria for flow down to subcontracts. Such a report would probably be prepared by company management, and would probably involve legal assistance to prepare and careful review at several levels. There are no recordkeeping requirements in the rule.

5. Description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the state objectives of applicable statute, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The Councils adopted the following alternatives in order to minimize the impact on small business concerns:

- The final rule requires small businesses to ''make a copy of the code available'' to each employee (rather than ''provide a copy''). The Councils rejected the addition of a requirement that small businesses must specifically make each employee aware of the duties and obligations under the code.
- The requirement for formal training programs and internal control systems is inapplicable to small business concerns. Large businesses are still required to have an ongoing business ethics and conduct awareness and compliance program
- *Disclosure* of violations of criminal law is limited to violations of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in 18 U.S.C., rather than any violation of criminal law.
- The violations that must be *disclosed* do not include violations under the contracts of other contractors.
- The period of occurrence of violations that must be *disclosed* is limited to 3 years after contract closeout, rather than extending indefinitely.

The Councils could not exclude small businesses that provide commercial items, because Pub. L. 110–252 requires application to contracts for the acquisition of commercial items.

The Councils decided to require disclosure of violations of civil False Claims Act (from both large and small businesses), *as requested by the Department of Justice,*

because to achieve the objectives of this rule, it is crucial to deal with responsible contractors, whether large or small. It is not necessarily evident at the beginning of an investigation whether an incident is simply an overpayment, a civil false claim, or a criminal violation. There is no rational reason to exclude civil false claims from the mandatory disclosure requirement.

Interested parties may obtain a copy of the FRFA from the FAR Secretariat. The FAR Secretariat has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

D. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. Chapter 35) applies because the final rule contains an information collection requirement (ICR). The clause at 52.203–13 requires the Contractor to disclose ''credible evidence of a violation'' of Federal criminal law or a violation of the False Claims Act, involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code. We received one comment from the public on this disclosure requirement. Based on the comment that the Government's estimated burden of 3 hours per response was inadequate, the Councils have revised the estimated burden hours to 60 hours per response. This change particularly considers the hours that would be required for review of the collection within a company, prior to release to the Government. Based on the revised estimated burden of 60 hours per response, the annual reporting burden is revised as follows:

Respondents:		284
Responses per respondent:	×	1
Total annual responses:		284
Preparation hours per response:	×	60
Total response burden hours:		17,040
Averages wages ($75 + 32.85% OH):	×	$100
Estimated cost to the Public:		$1,704,000

Accordingly, the FAR Secretariat has forwarded a request for approval of a new information collection requirement concerning 9000–00XX to the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 2, 3, 9, 42 and 52

Government procurement.

Al Matera,

Director, Office of Acquisition Policy.

■ Therefore, DoD, GSA, and NASA amend 48 CFR parts 2, 3, 9, 42 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 3, 9, 42 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 2. Amend section 2.101 in paragraph (b)(2) by adding, in alphabetical order, the definition ''Principal'' to read as follows:

2.101 Definitions.

* * * * *

(b) * * *

(2) * * *

Principal means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

* * * * *

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 3. Revise section 3.1001 to read as follows:

3.1001 Definitions.

As used in this subpart—

Subcontract means any contract entered into by a subcontractor to furnish supplies or services for performance of a prime contract or a subcontract.

Subcontractor means any supplier, distributor, vendor, or firm that furnished supplies or services to or for a prime contractor or another subcontractor.

United States means the 50 States, the District of Columbia, and outlying areas.

■ 4. Amend section 3.1003 by revising the section heading and paragraph (a); redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b) to read as follows:

3.1003 Requirements.

(a) *Contractor requirements.* (1) Although the policy at 3.1002 applies as guidance to all Government contractors, the contractual requirements set forth in the clauses at 52.203–13, Contractor Code of Business Ethics and Conduct, and 52.203–14, Display of Hotline Poster(s), are mandatory if the contracts meet the conditions specified in the clause prescriptions at 3.1004.

(2) Whether or not the clause at 52.203–13 is applicable, a contractor may be suspended and/or debarred for knowing failure by a principal to timely disclose to the Government, in connection with the award, performance, or closeout of a Government contract performed by the contractor or a subcontract awarded thereunder, credible evidence of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act. Knowing failure to timely disclose credible evidence of any of the above violations remains a cause for suspension and/or debarment until 3 years after final payment on a contract (see 9.406–2(b)(1)(vi) and 9.407–2(a)(8)).

(3) The Payment clauses at FAR 52.212–4(i)(5), 52.232–25(d), 52.232–26(c), and 52.232–27(l) require that, if the contractor becomes aware that the Government has overpaid on a contract financing or invoice payment, the contractor shall remit the overpayment amount to the Government. A contractor may be suspended and/or debarred for knowing failure by a principal to timely disclose credible evidence of a significant overpayment, other than overpayments resulting from contract financing payments as defined in 32.001 (see 9.406–2(b)(1)(vi) and 9.407–2(a)(8)).

(b) *Notification of possible contractor violation.* If the contracting officer is notified of possible contractor violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 U.S.C.; or a violation of the civil False Claims Act, the contracting officer shall—

(1) Coordinate the matter with the agency Office of the Inspector General; or

(2) Take action in accordance with agency procedures.

* * * * *

■ 5. Amend section 3.1004 by removing the introductory text and revising the introductory text of paragraph (b)(1) to read as follows:

3.1004 Contract clauses.

* * * * *

(b)(1) Unless the contract is for the acquisition of a commercial item or will be performed entirely outside the United States, insert the clause at FAR

52.203–14, Display of Hotline Poster(s), if—

* * * * *

PART 9—CONTRACTOR QUALIFICATIONS

■ 6. Amend section 9.104–1 by revising paragraph (d) to read as follows:

9.104–1 General standards.

* * * * *

(d) Have a satisfactory record of integrity and business ethics (for example, see Subpart 42.15).

* * * * *

■ 7. Amend section 9.406–2 by revising the introductory text of paragraph (b)(1) and adding paragraph (b)(1)(vi) to read as follows:

9.406–2 Causes for debarment.

(b)(1) A contractor, based upon a preponderance of the evidence, for any of the following—

* * * * *

(vi) Knowing failure by a principal, until 3 years after final payment on any Government contract awarded to the contractor, to timely disclose to the Government, in connection with the award, performance, or closeout of the contract or a subcontract thereunder, credible evidence of—

(A) Violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code;

(B) Violation of the civil False Claims Act (31 U.S.C. 3729–3733); or

(C) Significant overpayment(s) on the contract, other than overpayments resulting from contract financing payments as defined in 32.001.

* * * * *

■ 8. Revise section 9.407–2 by redesignating paragraph (a)(8) as paragraph (a)(9) and adding a new paragraph (a)(8); to read as follows:

9.407–2 Causes for suspension.

(a) * * *

(8) Knowing failure by a principal, until 3 years after final payment on any Government contract awarded to the contractor, to timely disclose to the Government, in connection with the award, performance, or closeout of the contract or a subcontract thereunder, credible evidence of—

(i) Violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code;

(ii) Violation of the civil False Claims Act (31 U.S.C. 3729–3733); or

(iii) Significant overpayment(s) on the contract, other than overpayments resulting from contract financing payments as defined in 32.001; or

* * * * *

PART 42—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 9. Amend section 42.1501 by revising the last sentence to read as follows:

42.1501 General.

* * * It includes, for example, the contractor's record of conforming to contract requirements and to standards of good workmanship; the contractor's record of forecasting and controlling costs; the contractor's adherence to contract schedules, including the administrative aspects of performance; the contractor's history of reasonable and cooperative behavior and commitment to customer satisfaction; the contractor's record of integrity and business ethics, and generally, the contractor's business-like concern for the interest of the customer.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 10. Amend section 52.203–13 by—

■ a. Revising the date of clause;

■ b. Revising paragraph (a);

■ c. Revising paragraphs (b)(1)(i), (b)(1)(ii), (b)(2) and adding paragraph (b)(3); and

■ d. Revising paragraphs (c) and (d).

The revised text reads as follows:

52.203–13 Contractor Code of Business Ethics and Conduct.

* * * * *

Contractor Code of Business Ethics and Conduct

(Dec 2008)

(a) *Definitions.* As used in this clause—

Agent means any individual, including a director, an officer, an employee, or an independent Contractor, authorized to act on behalf of the organization.

Full cooperation—(1) Means disclosure to the Government of the information sufficient for law enforcement to identify the nature and extent of the offense and the individuals responsible for the conduct. It includes providing timely and complete response to Government auditors' and investigators' request for documents and access to employees with information;

(2) Does not foreclose any Contractor rights arising in law, the FAR, or the terms of the contract. It does not require—

(i) A Contractor to waive its attorney-client privilege or the protections afforded by the attorney work product doctrine; or

(ii) Any officer, director, owner, or employee of the Contractor, including a sole proprietor, to waive his or her attorney client privilege or Fifth Amendment rights; and

(3) Does not restrict a Contractor from—

(i) Conducting an internal investigation; or

(ii) Defending a proceeding or dispute arising under the contract or related to a potential or disclosed violation.

Principal means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

Subcontract means any contract entered into by a subcontractor to furnish supplies or services for performance of a prime contract or a subcontract.

Subcontractor means any supplier, distributor, vendor, or firm that furnished supplies or services to or for a prime contractor or another subcontractor.

United States means the 50 States, the District of Columbia, and outlying areas.

(b) * * *

(1) * * *

(i) Have a written code of business ethics and conduct;

(ii) Make a copy of the code available to each employee engaged in performance of the contract.

(2) The Contractor shall—

(i) Exercise due diligence to prevent and detect criminal conduct; and

(ii) Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

(3)(i) The Contractor shall timely disclose, in writing, to the agency Office of the Inspector General (OIG), with a copy to the Contracting Officer, whenever, in connection with the award, performance, or closeout of this contract or any subcontract thereunder, the Contractor has credible evidence that a principal, employee, agent, or subcontractor of the Contractor has committed—

(A) A violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code; or

(B) A violation of the civil False Claims Act (31 U.S.C. 3729–3733).

(ii) The Government, to the extent permitted by law and regulation, will safeguard and treat information obtained pursuant to the Contractor's disclosure as confidential where the information has been marked ''confidential'' or ''proprietary'' by the company. To the extent permitted by law and regulation, such information will not be released by the Government to the public pursuant to a Freedom of Information Act request, 5 U.S.C. Section 552, without prior notification to the Contractor. The Government may transfer documents provided by the Contractor to any department or agency within the Executive Branch if the information relates to matters within the organization's jurisdiction.

(iii) If the violation relates to an order against a Governmentwide acquisition contract, a multi-agency contract, a multiple-award schedule contract such as the Federal Supply Schedule, or any other procurement instrument intended for use by multiple agencies, the Contractor shall notify the OIG of the ordering agency and the IG of the agency responsible for the basic contract.

(c) Business ethics awareness and compliance program and internal control

system. This paragraph (c) does not apply if the Contractor has represented itself as a small business concern pursuant to the award of this contract or if this contract is for the acquisition of a commercial item as defined at FAR 2.101. The Contractor shall establish the following within 90 days after contract award, unless the Contracting Officer establishes a longer time period:

(1) An ongoing business ethics awareness and compliance program.

(i) This program shall include reasonable steps to communicate periodically and in a practical manner the Contractor's standards and procedures and other aspects of the Contractor's business ethics awareness and compliance program and internal control system, by conducting effective training programs and otherwise disseminating information appropriate to an individual's respective roles and responsibilities.

(ii) The training conducted under this program shall be provided to the Contractor's principals and employees, and as appropriate, the Contractor's agents and subcontractors.

(2) An internal control system.

(i) The Contractor's internal control system shall—

(A) Establish standards and procedures to facilitate timely discovery of improper conduct in connection with Government contracts; and

(B) Ensure corrective measures are promptly instituted and carried out.

(ii) At a minimum, the Contractor's internal control system shall provide for the following:

(A) Assignment of responsibility at a sufficiently high level and adequate resources to ensure effectiveness of the business ethics awareness and compliance program and internal control system.

(B) Reasonable efforts not to include an individual as a principal, whom due diligence would have exposed as having engaged in conduct that is in conflict with the Contractor's code of business ethics and conduct.

(C) Periodic reviews of company business practices, procedures, policies, and internal controls for compliance with the Contractor's code of business ethics and conduct and the special requirements of Government contracting, including—

(*1*) Monitoring and auditing to detect criminal conduct;

(*2*) Periodic evaluation of the effectiveness of the business ethics awareness and compliance program and internal control system, especially if criminal conduct has been detected; and

(*3*) Periodic assessment of the risk of criminal conduct, with appropriate steps to design, implement, or modify the business ethics awareness and compliance program and the internal control system as necessary to reduce the risk of criminal conduct identified through this process.

(D) An internal reporting mechanism, such as a hotline, which allows for anonymity or confidentiality, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports.

(E) Disciplinary action for improper conduct or for failing to take reasonable steps to prevent or detect improper conduct.

(F) Timely disclosure, in writing, to the agency OIG, with a copy to the Contracting Officer, whenever, in connection with the award, performance, or closeout of any Government contract performed by the Contractor or a subcontractor thereunder, the Contractor has credible evidence that a principal, employee, agent, or subcontractor of the Contractor has committed a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 U.S.C. or a violation of the civil False Claims Act (31 U.S.C. 3729–3733).

(*1*) If a violation relates to more than one Government contract, the Contractor may make the disclosure to the agency OIG and Contracting Officer responsible for the largest dollar value contract impacted by the violation.

(*2*) If the violation relates to an order against a Governmentwide acquisition contract, a multi-agency contract, a multiple-award schedule contract such as the Federal Supply Schedule, or any other procurement instrument intended for use by multiple agencies, the contractor shall notify the OIG of the ordering agency and the IG of the agency responsible for the basic contract, and the respective agencies' contracting officers.

(*3*) The disclosure requirement for an individual contract continues until at least 3 years after final payment on the contract.

(*4*) The Government will safeguard such disclosures in accordance with paragraph (b)(3)(ii) of this clause.

(G) Full cooperation with any Government agencies responsible for audits, investigations, or corrective actions.

(d) *Subcontracts.* (1) The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts that have a value in excess of $5,000,000 and a performance period of more than 120 days.

(2) In altering this clause to identify the appropriate parties, all disclosures of violation of the civil False Claims Act or of Federal criminal law shall be directed to the agency Office of the Inspector General, with a copy to the Contracting Officer.

(End of clause)

■ 11. Amend section 52.209–5 by revising the date of clause; and paragraph (a)(2) to read as follows:

52.209–5 Certification Regarding Responsibility Matters.

* * * * *

Certification Regarding Responsibility Matters

(Dec 2008)

* * * * *

(a) * * *

(2) *Principal,* for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

* * * * *

■ 12. Amend section 52.212–5 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (b)(2) through (b)(40) as (b)(3) through (b)(41), respectively, and adding a new paragraph (b)(2);

■ c. Removing from paragraph (e)(1) ''paragraphs (i) through (vii)'' and adding ''paragraphs (e)(1)(i) through (xi)'' in its place; and.

■ d. Redesignating paragraphs (e)(1)(i) through (e)(1)(x) as paragraphs (e)(1)(ii) through (e)(1)(xi), respectively, and adding a new paragraph (e)(1)(i).

The added and revised text reads as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items

(Dec 2008)

* * * * *

(b) * * *

(2) 52.203–13, Contractor Code of Business Ethics and Conduct (DEC 2008)(Pub. L. 110–252, Title VI, Chapter 1 (41 U.S.C. 251 note)).

* * * * *

(e) * * *

(1) * * *

(i) 52.203–13, Contractor Code of Business Ethics and Conduct (DEC 2008) (Pub. L. 110–252, Title VI, Chapter 1 (41 U.S.C. 251 note)).

* * * * *

52.213–4 [Amended]

■ 13. Amend section 52.213–4 by—

■ a. Revising the date of the clause to read (DEC 2008); and

■ b. Removing from paragraph (a)(2)(vi) ''(MAR 2007)'' and adding ''(DEC 2008)'' in its place.

■ 14. Amend section 52.244–6 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (c)(1)(i) through (c)(1)(vi) as paragraphs (c)(1)(ii) through (c)(1)(vii), respectively, and adding a new paragraph (c)(1)(i).

The added and revised text reads as follows:

52.244–6 Subcontracts for Commercial Items.

* * * * *

Subcontracts for Commercial Items

(Dec 2008)

* * * * *

(c)(1) * * *

(i) 52.203–13, Contractor Code of Business Ethics and Conduct (DEC 2008) (Pub. L. 110–252, Title VI, Chapter 1 (41 U.S.C. 251 note).

* * * * *

[FR Doc. E8–26953 Filed 11–10–08; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2008–0003, Sequence 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–28; Small Entity Compliance Guide

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of the Secretary of Defense, the Administrator of General Services and the Administrator of the National Aeronautics and Space Administration. This Small Entity Compliance Guide has been prepared in accordance with Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rule appearing in Federal Acquisition Circular (FAC) 2005–28 which amends the FAR. An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared. Interested parties may obtain further information regarding this rule by referring to FAC 2005–28 which precedes this document. These documents are also available via the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Laurieann Duarte, Regulatory Secretariat, (202) 501–4225. For clarification of content, contact the analyst whose name appears in the table below.

RULE LISTED IN FAC 2005–28

Item	Subject	FAR case	Analyst
*I	Contractor Business Ethics Compliance Program and Disclosure Requirements	2007–006	Woodson.

SUPPLEMENTARY INFORMATION: A summary of the FAR rule follows. For the actual revisions and/or amendments to this FAR case, refer to FAR Case 2007–006.

FAC 2005–28 amends the FAR as specified below: Item I—Contractor Business Ethics Compliance Program and Disclosure Requirements (FAR Case 2007–006)

This final rule amends the Federal Acquisition Regulation to amplify the requirements for a contractor code of business ethics and conduct, an internal control system, and disclosure to the Government of certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. The rule provides for the suspension or debarment of a contractor for knowing failure by a principal to timely disclose, in writing, to the agency Office of the Inspector General, with a copy to the contracting officer, certain violations of criminal law, violations of the civil False Claims Act, or significant overpayments. The final rule implements ''The Close the Contractor Fraud Loophole Act,'' Public Law 110–252, Title VI, Chapter 1. The statute defines a covered contract to mean ''any contract in an amount greater than $5,000,000 and more than 120 days in duration.'' The final rule also provides that the contractor's Internal Control System shall be established within 90 days after contract award, unless the Contracting Officer establishes a longer time period (*See* FAR 52.203–13(c)). The internal control system is not required for small businesses or commercial item contracts.

Dated: November 5, 2008.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E8–26809 Filed 11–10–08; 8:45 am]

BILLING CODE 6820–EP–P

Federal Register

Wednesday,
November 12, 2008

Part IV

The President

Notice of November 10, 2008—Continuation of National Emergency with Respect to Weapons of Mass Destruction

Federal Register
Vol. 73, No. 219
Wednesday, November 12, 2008

Presidential Documents

Title 3—

The President

Notice of November 10, 2008

Continuation of National Emergency with Respect to Weapons of Mass Destruction

On November 14, 1994, by Executive Order 12938, the President declared a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the proliferation of nuclear, biological, and chemical weapons (weapons of mass destruction) and the means of delivering such weapons. On July 28, 1998, the President issued Executive Order 13094 amending Executive Order 12938 to respond more effectively to the worldwide threat of weapons of mass destruction proliferation activities. On June 28, 2005, I issued Executive Order 13382 that, *inter alia*, further amended Executive Order 12938 to improve our ability to combat proliferation. The proliferation of weapons of mass destruction and the means of delivering them continues to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States; therefore, the national emergency first declared on November 14, 1994, and extended in each subsequent year, must continue. In accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 12938, as amended.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
November 10, 2008.

[FR Doc. E8–27046
Filed 11–10–08; 11:15 am]
Billing code 3195–W9–P

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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.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 6197/P.L. 110–448

To designate the facility of the United States Postal Service

located at 7095 Highway 57 in Counce, Tennessee, as the "Pickwick Post Office Building". (Oct. 22, 2008; 122 Stat. 5013)

Last List October 23, 2008

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