



Federal Register

1-2-09

Vol. 74 No. 1

Friday

Jan. 2, 2009

Pages 1-200



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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WHEN: Tuesday, January 27, 2009
9:00 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741-6008



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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 83, and 93

[Docket No. APHIS–2007–0038]

RIN 0579–AC74

Viral Hemorrhagic Septicemia; Interstate Movement and Import Restrictions on Certain Live Fish

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule; delay of effective date.

SUMMARY: On September 9, 2008, we published an interim rule in the **Federal Register** to restrict the interstate movement and importation into the United States of live fish that are susceptible to viral hemorrhagic septicemia, a highly contagious disease of certain freshwater and saltwater fish. That interim rule was scheduled to become effective on November 10, 2008. Subsequently, on October 28, 2008, we published a notice in the **Federal Register** announcing the delay of the effective date of the interim rule until January 9, 2009. We are now delaying the effective date of the interim rule indefinitely to provide APHIS with time to make some adjustments to the interim rule that are necessary for the rule to be successfully implemented.

DATES: The effective date for the interim rule amending 9 CFR parts 71, 83, and 93, published at 73 FR 52173–52189 on September 9, 2008, is delayed indefinitely.

FOR FURTHER INFORMATION CONTACT: Dr. P. Gary Egrie, Senior Staff Veterinary Medical Officer, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231; (301) 734–0695; or Dr. Peter L. Merrill, Senior Staff

Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

SUPPLEMENTARY INFORMATION:

Background

Viral hemorrhagic septicemia (VHS) is a highly contagious disease of certain freshwater and saltwater fish, caused by a rhabdovirus. It is listed as a notifiable disease by the World Organization for Animal Health. The pathogen produces variable clinical signs in fish including lethargy, skin darkening, exophthalmia, pale gills, a distended abdomen, and external and internal hemorrhaging. The development of the disease in infected fish can result in substantial mortality. Other infected fish may not show any clinical signs or die, but may be lifelong carriers and shed the virus.

On September 9, 2008, we published an interim rule in the **Federal Register** (73 FR 52173–52189, Docket No. APHIS–2007–0038) to amend 9 CFR parts 71, 83, and 93 by establishing regulations to restrict the interstate movement and the importation into the United States of certain live fish species that are susceptible to VHS. We announced that the provisions of the interim rule would become effective November 10, 2008, and that we would consider all comments on the interim rule received on or before November 10, 2008, and all comments on the environmental assessment for the interim rule received on or before October 9, 2008.

Delay of Effective Date

After the publication of the interim rule, we received comments that addressed a variety of issues, including the feasibility of implementing certain requirements.

Based on our review of those comments, on October 28, 2008, we published a document in the **Federal Register** (73 FR 63867, Docket No. APHIS–2007–0038) announcing that we were delaying the effective date of the interim rule from November 10, 2008, until January 9, 2009, while retaining November 10, 2008 as the close of the comment period for the interim rule and October 9, 2008 as the close of the comment period for the environmental assessment.

We are now delaying the effective date of the interim rule indefinitely to

provide APHIS with time to make some adjustments to the interim rule that are necessary for the rule to be successfully implemented.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–31208 Filed 12–31–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS–2007–0095]

RIN 0579–AC63

Importation of Cattle From Mexico; Addition of Port at San Luis, AZ

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of cattle from Mexico by adding San Luis, AZ, as a port through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported into the United States. A new facility for the handling of animals is to be constructed on the Mexican side of the border at the port of San Luis, AZ, that will be equipped with facilities necessary for the proper chute inspection, dipping, and testing that are required for such cattle under the regulations. We are also amending the regulations to remove provisions that limit the admission of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas. The statutory requirement that limited the admission of those cattle to the State of Texas has been repealed. These changes will make an additional port of entry available and relieve restrictions on the movement of imported Mexican cattle within the United States.

DATES: *Effective Date:* This rule is effective January 2, 2009 except for the amendment (amendatory instruction 3)

to § 93.427(b)(2) introductory text, for which the effective date is delayed indefinitely. The Animal and Plant Health Inspection Service will publish a document announcing an effective date for that provision in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Dr. Betzaida Lopez, Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231; (301) 734-8364.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 93 prohibit or restrict the importation of certain animals, birds, and poultry into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart D of part 93 (§§ 93.400 through 93.436, referred to below as the regulations) governs the importation of ruminants; within subpart D, §§ 93.424 through 93.429 specifically address the importation of various ruminants from Mexico into the United States.

In § 93.426, paragraph (a) states that all ruminants offered for entry into the United States from Mexico must be inspected at the port of entry and found to be free from communicable diseases and fever tick infestation and to not have been exposed to communicable diseases and fever tick infestation. Ruminants found to be affected with or to have been exposed to a communicable disease, or infested with fever ticks, are to be refused entry except as provided in § 93.427(b)(2).

Under § 93.427(b)(2), cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the State of Texas, except that portion of the State quarantined because of fever ticks, either at one of the land border ports in Texas listed in § 93.403(c) of the regulations, or at the port of Santa Teresa, NM, provided that certain conditions are met. Those conditions are spelled out in paragraphs (b)(2)(i) through (b)(2)(v) of § 93.427.

On January 9, 2008, we published in the **Federal Register** (73 FR 5132-5135, Docket No. APHIS-2007-0095) a proposal¹ to amend the regulations by adding San Luis, AZ, as a port through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported

into the United States. A new facility for the handling of animals is to be constructed on the Mexican side of the border at the port of San Luis, AZ, that will be equipped with facilities necessary for the chute inspection, dipping, and testing that are required for such cattle under the regulations. We also proposed to amend the regulations to remove provisions that limit the admission of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas. The statutory requirement that limited the admission of those cattle to the State of Texas has been repealed. These changes were intended to make an additional port of entry available and relieve restrictions on the movement of imported Mexican cattle within the United States.

We solicited comments concerning our proposal for 60 days ending March 31, 2008. We received 52 comments by that date. They were from private citizens, industry groups, and State agriculture organizations.

Thirty-eight commenters supported the proposed rule. Fourteen commenters expressed concerns regarding the proposed rule. The issues they raised are discussed below.

One commenter objected to allowing cattle infested with fever ticks to be imported into the United States.

The regulations currently allow cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, to be imported into the United States; we proposed to allow their importation through the port of San Luis. However, the animals would have to meet the requirements in the regulations for inspection, dipping, and certification of freedom from ticks before entering the United States.

Many commenters expressed concern that the opening of the new port at San Luis may cause an increase in the number of Mexican cattle imported into the United States annually, particularly because it would reduce the cost to ship for some entities. The commenters also stated that this increase could cause financial harm to cattle ranchers in the United States or damage the international reputation of the U.S. cattle industry. Several commenters expressed concern with the risk assessment, stating that its conclusion that the rule would not increase risk was based on a faulty assumption that the new port would not lead to an increase in the volume of cattle exports from Mexico.

In response to these comments, we have prepared an addendum to the risk

assessment,² which gives additional details regarding the reasons we do not expect this rule to increase the number of Mexican cattle imported into the United States. As the addendum states, increases or decreases in Mexican cattle import volumes are due to a number of factors, most importantly weather, the financial situation of Mexican cattle farmers, and the price of feeder cattle in the southwestern United States. In addition, although imports have increased over time, the total export market for Mexican cattle is not expected to increase in the future because the demand for domestic beef within Mexico continues to increase. Mexican beef calf exports are almost all destined for the United States already. Therefore, it is unlikely that Mexican cattle producers will have a large number of additional cattle available for export to the United States.

In addition, even if the export market were to increase, we would not expect large numbers of cattle to enter the United States through San Luis. Currently, the majority of Mexican cattle (about 80 percent) are destined for New Mexico or Texas ports, with only a small percentage (about 15 percent) going to ports in more westerly States, including Arizona and California. This is because the mountainous terrain and lack of well-developed roads running east to west within Mexico make it difficult for cattle from eastern States of Mexico, where the majority of cattle are produced, to utilize ports in more westerly States within the U.S. If these trends continue, we would expect the bulk of the increase in Mexican cattle imports to continue to enter through New Mexico and Texas ports based on proximity, cost, and convenience of travel. The Mexican States that are closest to the San Luis port and that would, therefore, be most likely to use the San Luis port are: Baja California Norte, Baja California Sur, Nayarit, Sinaloa, and Sonora. Because these five Mexican States account for only about 14 percent of Mexican cattle production, even if they were to increase their cattle exports, it is unlikely that there will be a significant increase in the number of Mexican cattle exported to the United States as a result of our opening the port of San Luis to cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks.

One commenter asked what impact the proposed rule would have on the price of cattle and beef.

¹ To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0095>.

² See footnote 1 for the address to view the risk assessment and the addendum to the risk assessment.

Since the amount of cattle entering the United States from Mexico is not expected to increase significantly as a result of this final rule, cattle prices should not be greatly affected. However, some importers who have been importing Mexican cattle into the United States through ports in Texas and New Mexico may save some shipping costs by switching to the port in San Luis. To the extent that these savings on shipping costs are passed on by brokers, consumers could see lower prices.

Several commenters expressed concern that allowing cattle to be imported through the port at San Luis would result in more Mexican cattle moving to areas in the United States conducive to tick establishment.

We expect most of the cattle that will be imported through the port at San Luis will be cattle that otherwise would have been imported through Texas or New Mexico ports, and not cattle that would otherwise not have been imported. Because brokers importing cattle from Mexico usually supply cattle to the same entities they have previously dealt with, we do not expect the U.S. destination of Mexican cattle to change as a result of this rule. As stated in the addendum to the risk assessment, cattle imported through the port at San Luis will most likely be bound for California or other areas of Arizona where non-exposed cattle and cattle not previously infested with fever ticks and found to be eligible for importation have historically gone. Although there are areas within Southern California that may be conducive to fever tick establishment, fever ticks within the United States have been confined to certain quarantined areas in Texas since 1943 despite continual importation of Mexican cattle into the United States.

As stated previously, even if cattle infested with fever ticks are presented for importation, they would have to meet the requirements in the regulations for inspection, dipping, and certification of freedom from ticks of any type before entering the United States. Although dipping cattle with acaricide is not considered 100 percent effective against ticks, these measures are the same requirements for cattle entering at other ports. Therefore, opening the port at San Luis to Mexican cattle that have been infested with fever ticks or exposed to fever or tick-borne diseases does not present an additional risk of introduction and spread of fever ticks or introduction and spread of tick fever.

Several commenters expressed concern that the area around the proposed San Luis port may also be

conducive to tick establishment if cattle remain in the area.

As stated in the risk assessment, the area surrounding the port of San Luis is not suitable for the establishment of fever ticks. This is because precipitation levels in the area around the port are too low to support the establishment of fever ticks. While moisture from the Colorado River and from private wells in the area may create micro-habitats that could increase the chance of survival for fever ticks, cattle imported through the port at San Luis are not likely to remain near the port. Finally, even if tick-infested cattle were imported and did remain near the port at San Luis, they, along with all other cattle imported through the port, would have been inspected, dipped, and certified as free from ticks of any type before entering the United States. As stated previously, although not 100 percent effective against ticks, these are the same requirements for cattle entering at other ports. Therefore, there is no additional risk of introduction and spread of fever ticks or introduction and spread of tick fever.

Two commenters stated that tick fever outbreaks have occurred in areas of the United States and Europe above the 36° N line of latitude, which contradicts the findings in the risk assessment. One of these commenters asked that the risk assessment be revised to address this issue.

There has never been an outbreak of fever ticks or tick fever within the United States above the 36° N line of latitude that has been conclusively linked to cattle imported from Mexico. As mentioned in the risk assessment, the environment above the 36° N line of latitude is not conducive for the establishment of fever ticks, even in the case that some ticks might make it across the border. This is because fever ticks thrive in tropical and subtropical climates; at temperatures below 20 °C, the reproductive ability of female ticks appears to be impaired.

As noted by the commenter, tick fever outbreaks have been reported in areas of Europe above the 36° N line of latitude (*i.e.*, Finland, the Netherlands, Romania, and Slovenia); however those outbreaks were due to species of *Babesia* (*Babesia divergens* and *B. jakimovi*) that are transmitted via a different, non-*Boophilus* species of tick (*Ixodes ricinus*) capable of thriving in more northern climates. Neither these *Babesia* species nor this tick species are indigenous to the United States, although similar tick species such as *I. (dammini) scapularis* and *I. pacificus* are present that feed on deer and mice, and are capable of spreading another

species of *Babesia*, *B. microti*. However, unlike with other *Babesia* species that cause tick fever, humans and not cattle are the intermediate hosts for *B. microti*.

One commenter expressed concern that the restriction limiting the importation of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas was lifted without allowing for public comment.

As stated in the proposed rule, the passage of the North American Free Trade Agreement (NAFTA) Implementation Act removed the statutory provisions that limited the importation of cattle only into the State of Texas. Following the passage of the NAFTA Implementation Act, our permitting procedures were modified to allow cattle that had been infested with or exposed to fever ticks to be moved from Mexico into States other than Texas under the conditions described in § 93.427(b)(2). However, we did not make a corresponding change in the regulations to reflect the statutory amendment. We sought to rectify this error in this rulemaking, which also allowed the public the opportunity to comment on the removal of the restriction.

Several commenters expressed concern regarding acaricide-resistant ticks present in Mexico. One commenter suggested that we require Mexico to standardize their tick treatment protocol for exported cattle according to the recommendations of the Binational Tick Committee, which requires a 400 ppm Amitraz immersion.

Although there is a concern about acaricide-resistant ticks in Mexico, the resistance has proven to be due to the inappropriate use of acaricides. The Mexican Government has developed a pesticide resistance management program to minimize the development and spread of resistant tick populations. We expect that these changes will ensure that acaricides continue to be an effective treatment for cattle imported into the United States. Cattle from Mexico are currently being treated with at least a 400 ppm Amitraz treatment before entering the United States.

Several commenters stated that the Cattle Fever Tick Eradication Program must be fully funded and implemented.

We will continue to seek full funding of our tick eradication program and, in the event of a fever tick outbreak, will take appropriate action to eliminate the outbreak.

One commenter asked if more information was available about the economic effects of the proposed rule on small businesses. Another commenter stated that a cost-benefit analysis should

be conducted before the proposed rule is finalized. One commenter stated that our estimate of the costs of eradicating ticks from infested herds is inadequate because it is based on 2005 data and because it did not include the costs of replacing animals lost to tick fever.

The initial regulatory flexibility analysis in the proposed rule provided all the information that was available to us regarding the potential economic effects of the proposed rule on small businesses. The cost data in the regulatory flexibility analysis was based on the most current data available at the time of drafting. Although some of this data might be from 2005, this does not impact the regulatory flexibility analysis. Despite the costs, we will continue to use all the resources at our disposal to prevent the introduction and dispersal of tick fever into the United States. Moreover, we note that there has never been an outbreak of tick fever in the United States that was conclusively linked to Mexican-origin cattle.

One commenter expressed concern that the United States could experience lost export markets because it does not follow World Organization of Animal Health (OIE) guidelines with regard to tick fever. In particular, the commenter mentioned the OIE guidelines recommending that a country limit its imports to animals that have resided since birth in a zone recognized as free from tick fever or to animals that have tested negative for tick fever in the preceding month, and that have been treated with an acaricide prior to shipment.

In order for bovine babesiosis to persist in cattle populations in the United States, three factors must simultaneously exist: Agent, host, and environment. In the absence of all three elements, it is still possible for disease to be detected occasionally, but difficult for the infection to persist in a population. Fever ticks are currently confined to quarantined areas within Texas and movement restrictions are in place to prevent the movement of cattle from Mexico into the quarantined areas. As stated in the risk assessment, in the absence of vector ticks, tick-borne diseases cannot be spread and, therefore, will gradually disappear from an infected herd. Therefore, even if an animal was a carrier of tick fever, because there are no vectors to transmit the disease within the United States outside of the quarantined areas and because there are restrictions in place to prevent the movement of Mexican cattle into or through tick quarantine areas, it is unlikely that tick fever would be introduced and spread within the United States. We are not aware of

having lost any export markets due to not complying with OIE guidelines. Moreover, we do not believe it is necessary to limit U.S. cattle imports to animals that have resided since birth in a zone recognized as free from tick fever or to those cattle that have tested negative for tick fever prior to importation.

Several commenters stated that the prohibition on the movement of tick-infested cattle into the area of Texas quarantined for cattle tick fever must be maintained.

We agree with the commenter, as we are continuing eradication efforts in that area of Texas. Therefore, this rule continues the prohibition on the movement from Mexico of tick-infested cattle or cattle that have been exposed to fever ticks or tick-borne diseases into the quarantined areas of Texas.

Several commenters stated that APHIS should work closely with Mexico to ensure that new cattle-handling facilities, including the port at San Luis, AZ, are properly managed, equipped, and funded to prevent the spread of cattle fever ticks into the United States and that port staff are adequately trained. One commenter stated that all port staff should be full-time and that APHIS should conduct regular reviews of procedures at the port at San Luis, AZ.

All ports on the Mexican border are staffed by APHIS as well as employees of the Mexican Government, and APHIS guidelines are in place to ensure consistency and close coordination between the two groups. In addition, APHIS has standard operating procedures in place that detail proper tick inspection procedures. All ports are staffed with full-time employees, and port facility reviews are conducted on a regular basis to make sure the facilities themselves and the procedures they employ are adequate to prevent the introduction of cattle fever ticks into the United States. The San Luis port, like all other ports that handle Mexican cattle, will undergo an inspection and approval process prior to being opened for trade.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Effective Dates

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

Immediate removal of the provision in § 93.427(b) that limited the admission of certain Mexican-origin cattle to parts of

Texas will make our regulations consistent with the NAFTA Implementation Act and with our permitting procedures, which were modified following the passage of the NAFTA implementation Act.

However, we are delaying, indefinitely, the effective date of the addition of San Luis, AZ, to the list in § 93.427(b) of ports through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported from Mexico, pending construction of new facilities and APHIS inspection of those facilities to confirm that they are properly equipped to allow for the necessary chute inspection, dipping, and testing of cattle.

Executive Order 12866 and Regulatory Flexibility Act

This final 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.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is set out below, regarding the economic effects of this rule on small entities.

For the purpose of this analysis, and following Small Business Administration (SBA) guidelines, the potentially affected entities are classified as Beef Cattle Ranching and Farming (North American Industry Classification System 112111). By SBA standards, farms in this category are considered small if annual receipts are not more than \$750,000. According to the 2002 Census of Agriculture, of the 664,431 beef cattle farms, 659,009, or 99 percent, had annual receipts of less than \$500,000 and are therefore considered small. Cattle imported into the United States from Mexico are generally purchased by stocker operations before they are shipped to feedlots. While there is no economic information available on the number, size, or distribution of the stocker operations, it is reasonable to assume they are small given that 99 percent of beef cattle ranches and farms in general are small entities.

From 2000 to 2006, an average of 45,258 cattle per year entered through the port of San Luis, Arizona.³ Historically, 80 percent of U.S. cattle imports from Mexico have gone to Texas and New Mexico. Between 2003 and 2008, over 6.5 million cattle entered the United States from Mexico at various

³ Source: Centers for Epidemiology and Animal Health Import Tracking System.

ports. The ports with the largest volume of cattle imports between 1994 and 2003 were Santa Teresa/El Paso (26.64 percent), Presidio (18.12 percent), and Nogales (14.24 percent). Only 5.95 percent of U.S. cattle imports from Mexico came through San Luis.⁴ To date, the San Luis port has only received 8,000 head of cattle in 2008. As mentioned in the addendum to the risk assessment, San Luis' western location makes it inconvenient, and therefore unlikely, that there will be a major shift in cattle movements from existing ports in Texas and New Mexico.

Any positive effects of the rule for small entities in the San Luis area, such as increased volumes of business for firms that transport cattle, are expected to be largely matched by business declines for firms operating from the Texas and New Mexico ports. Cattle importers who find it advantageous to use the San Luis port will be positively affected. There may also be positive effects at the Texas and New Mexico ports if the diversion of imports to San Luis of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases reduces operational delays when the demand for imports is beyond the capacity of those border facilities; however, APHIS has no information on whether such periods of insufficient capacity have occurred, and if so, how frequently.

The final rule will increase the number of cattle operations allowed to receive cattle from Mexico that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases. A larger number of more widely distributed U.S. entities will be afforded the opportunity to benefit from importing these cattle. Establishment of San Luis, AZ, as a port of entry for cattle from Mexico that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases will also make these cattle more readily accessible for entities to the west of Texas; transport costs from the port of entry will be lower because the cattle will be moved over shorter distances.

The Mexican Government has requested that a land-border port be established on the Mexico-Arizona border to move cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases from Mexico to the United States. APHIS has determined that with the construction of new facilities at the port of San Luis, this request can be satisfied given that the new port will be equipped to handle

cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases. The potential impacts for affected U.S. cattle operations, most of which are small entities, are expected to be positive. This rule does not contain any new reporting, recordkeeping, or compliance requirements. There are no significant alternatives to the rule that will accomplish the stated objectives.

Executive Order 12988

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

Paperwork Reduction Act

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

List of Subjects in 9 CFR Part 93

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

■ Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.427 is amended, effective January 2, 2009 by revising paragraph (b)(2) to read as follows:

§ 93.427 Cattle from Mexico.

* * * * *

(b) * * *

(2) Cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the United States, except into areas of Texas quarantined because of said disease or tick infestation as specified in § 72.5 of this chapter, either at one of the land border ports in Texas listed in § 93.403(c) or at the port of Santa

Teresa, NM, provided that the following conditions are strictly observed and complied with:

(i) The cattle shall be accompanied by a certificate issued in accordance with § 93.405(a), and showing that the veterinarian issuing the certificate has inspected the cattle and found them free from fever ticks and any evidence of communicable disease, and that, as far as it has been possible to determine, they have not been exposed to any such disease, except splenetic, southern, or tick fever, during the 60 days immediately preceding their movement to the port of entry.

(ii) The cattle shall be shown by a certificate issued in accordance with § 93.405(a) to have been dipped in a tickicidal dip within 7 to 12 days before being offered for entry.

(iii) The importer, or his or her duly authorized agent, shall first execute and deliver to an inspector at the port of entry an application for inspection and supervised dipping wherein he or she shall agree to waive all claims against the United States for any loss or damage to the cattle occasioned by or resulting from dipping, or resulting from the fact that they are later found to be still tick infested; and also for all subsequent loss or damage to any other cattle in the possession or control of such importer which may come into contact with the cattle so dipped.

(iv) The cattle when offered for entry shall receive a chute inspection by an inspector. If found free from ticks they shall be given one dipping in one of the permitted dips listed in § 72.13(b) of this chapter under the supervision of an inspector 7 to 14 days after the dipping required by paragraph (b)(2)(ii) of this section. The selection of the permitted dip to be used will be made by the port veterinarian in each case. If found to be infested with fever ticks, the entire lot of cattle shall be rejected and will not be again inspected for entry until 10 to 14 days after they have again been dipped in the manner provided by paragraph (b)(2)(ii) of this section.

(v) The conditions at the port of entry shall be such that the subsequent movement of the cattle can be made without exposure to fever ticks.

* * * * *

■ 3. Section 93.427 is further amended, with an effective date pending further notice, by revising paragraph (b)(2) introductory text to read as follows:

§ 93.427 Cattle from Mexico.

* * * * *

(b) * * *

(2) Cattle that have been exposed to splenetic, southern, or tick fever, or that

⁴ Source: Live cattle imports by Port of Entry from Mexico into the United States: Data and Models, New Mexico State University, August 2005.

have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the United States, except into areas of Texas quarantined because of said disease or tick infestation as specified in § 72.5 of this chapter, either at one of the land border ports in Texas listed in § 93.403(c) or at the port of Santa Teresa, NM, provided that the following conditions are strictly observed and complied with:

* * * * *

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,
Acting Administrator, Animal and Plant Health Inspection Service.
[FR Doc. E8-31212 Filed 12-31-08; 8:45 am]
BILLING CODE 3410-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2008-N-0039]

New Animal Drugs for Use in Animal Feeds; Tiamulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Novartis Animal Health US, Inc. The supplemental NADAs provide for

removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling of tiamulin medicated feeds used for the treatment or control of certain bacterial enteric diseases in swine.

DATES: This rule is effective January 2, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 139-472 for DENAGARD (tiamulin) Medicated Premixes used for the treatment or control of certain bacterial enteric diseases in swine. Novartis Animal Health US, Inc., also filed a supplement to NADA 141-011 for the use of DENAGARD (tiamulin) Medicated Premixes and Chlortetracycline Type A medicated articles to manufacture 2-way combination drug medicated swine feeds used for the treatment or control of certain bacterial enteric diseases. The supplemental NADAs provide for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling. The supplemental NADAs are approved as of December 9, 2008, and 21 CFR 558.600 is amended to reflect the approval.

Approval of these supplemental NADAs did not require review of additional safety or effectiveness data or

information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801 808.

List of Subjects in 21 CFR Part 558

Animal drugs, animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. In § 558.600, revise paragraphs (d)(2) and (e)(1)(i) to read as follows:

§ 558.600 Tiamulin.

* * * * *

(d) * * *

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

* * * * *

(e) * * *

(1) * * *

Tiamulin grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10	For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds.	058198

* * * * *

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Dated: December 22, 2008.
Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. E8-31128 Filed 12-31-08; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2008-N-0517]

Medical Devices; Immunology and Microbiology Devices; Classification of Enterovirus Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying enterovirus nucleic acid assay into class II (special controls). The special control that will apply to the device is the guidance document entitled “Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA” (ribonucleic acid). The agency is classifying the device into class II (special controls) in order to provide a

reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This final rule is effective February 2, 2009. The classification was effective March 16, 2007.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0725.

SUPPLEMENTARY INFORMATION:

I. What is the Background of This Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k) and part 807 (21 CFR part 807)).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on March 9, 2007, classifying the Xpert EV™ Assay as class III, because it was not

substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. Cepheid submitted a petition dated March 9, 2007, requesting classification of the Xpert EV™ Assay under section 513(f)(2) of the act. FDA filed the petition on March 12, 2007. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Xpert EV™ Assay can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name "enterovirus nucleic acid assay." It is identified as a device that consists of primers, probes, enzymes, and controls for the amplification and detection of enterovirus RNA in cerebrospinal fluid (CSF) from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

Failure of nucleic acid assays for detection of enterovirus RNA to perform as expected, or failure to interpret results correctly, may lead to incorrect patient management decisions. A false negative report could lead to delays in providing (or even failure to provide) a definitive diagnosis, and the unnecessary treatment of the patient with antibiotics. A false positive report could lead to a delayed treatment of bacterial meningitis or other forms of meningitis. This delayed treatment due to a false positive result could cause progression of potentially life-threatening bacterial meningitis with subsequent severe morbidity to the patient and potentially even patient death. Device failure leading to no result (for example, due to failure of reagents, instrumentation, data management, or

software) or an invalid or equivocal result could delay diagnosis, and could require an additional collection of CSF fluid, a procedure that is associated with the risk of infection. Furthermore, the appearance of new serotypes of enterovirus may affect the performance of an enterovirus nucleic acid amplification assay for the detection of enterovirus RNA in CSF specimens. Primers and probes for detection of enteroviruses are selected for their homology with highly conserved regions within viral RNA segments that are present in most enterovirus serotypes. Primers and probes might not detect new serotypes that appear over time. In addition, test performance can be affected, as the epidemiology and pathology of disease caused by the new enterovirus serotypes could change.

FDA believes the class II special controls guidance document will aid in mitigating potential risks by providing recommendations on labeling and validation of performance characteristics. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph. Therefore, on March 16, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 866.3225.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an enterovirus nucleic acid assay will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket review of the system's key performance characteristics, test methodology, labeling, and other requirements as outlined in § 807.87, will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type

of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the gene expression profiling test system for breast cancer prognosis they intend to market.

II. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) 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.

III. What is the Economic Impact of This Rule?

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 as defined by 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 classification of this device type into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, 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.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. Federal law includes an express preemption provision that preempts certain state requirements “different from, or in addition to” certain federal requirements applicable to devices. See 21 U.S.C. 360k; *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 128 S.Ct. 999 (2008).

In this rulemaking, FDA has determined that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish special controls to provide such assurance. FDA has therefore imposed a special control to address the amplification and detection of enterovirus RNA in CSF from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

As with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. See *Geier v. American Honda Co.*, 529 U.S. 861, (2000); *English v. General Electric Co.*, 496 U.S. 72, 79 (1990), *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–143 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This

guidance entitled “Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA” references previously approved collections of information found in FDA regulations.

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Cepheid, dated March 9, 2007.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3225 is added to subpart D to read as follows:

§ 866.3225 Enterovirus nucleic acid assay.

(a) *Identification.* An enterovirus nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of enterovirus ribonucleic acid (RNA) in cerebrospinal fluid (CSF) from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA.” See § 866.1(e) for the availability of this guidance document.

Dated: December 16, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–31213 Filed 12–31–08; 8:45 am]

BILLING CODE 4160-01-S

AGENCY FOR INTERNATIONAL DEVELOPMENT**22 CFR Part 215**

RIN 0412-AA61

Privacy Act of 1974, Implementation of Exemptions**AGENCY:** United States Agency for International Development.**ACTION:** Final rule.

SUMMARY: The United States Agency for International Development (USAID) has established a new system of records (see 72 FR 39042) pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), entitled the "Partner Vetting System". USAID published a proposed rule on July 20, 2007 (see 72 FR 39769) and is issuing this final rule after thorough review of all comments and suggestions received by the Agency through the public notice process and outreach sessions held for interested individuals. The final rule exempts portions of this system of records from one or more provisions of the Privacy Act. The decision as to whether to implement PVS will be made by the incoming Obama Administration.

DATES: This final rule will go into effect February 2, 2009.

FOR FURTHER INFORMATION CONTACT: Jeff Denale, Coordinator for Counterterrorism, Office of Security, United States Agency for International Development, Ronald Reagan Building, 1300 Pennsylvania Avenue, NW., Washington, DC 20523, telephone: (202) 712-1264.

SUPPLEMENTARY INFORMATION:**A. Background**

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, USAID established a new system of records (see 72 FR 39042), entitled the "Partner Vetting System" (PVS). The PVS would support the vetting of individuals and directors, officers, or other principal employees of non-governmental organizations (NGOs) who apply for USAID contracts, grants, cooperative agreements, or other funding and of NGOs who apply for registration with USAID as Private and Voluntary Organizations. The information collected for these individuals would be used to conduct screening to ensure USAID funds and USAID-funded activities are not purposefully or inadvertently used to provide support to entities or individuals deemed to be a risk to national security. As these individuals and organizations are neither employees of USAID or job applicants for jobs with

USAID, nor would they be eligible for or require security clearances, traditional employment or security clearance investigative mechanisms are not authorized or appropriate for the stated purposes.

USAID will exempt portions of the PVS from certain provisions of the Privacy Act and add the PVS to 22 CFR 215.13, General Exemptions, and 22 CFR 215.14, Specific Exemptions. USAID requires this exemption from the Privacy Act in order to protect information, recompiled from records of other government agencies and related to investigations, from disclosure to subjects of investigations and to protect classified information related to the government's national security programs. Specifically, the exemptions are required to preclude subjects of investigations from frustrating the investigative process; to avoid disclosure of investigative techniques; protect the identities and physical safety of confidential informants and of law enforcement personnel; ensure the ability of USAID's Office of Security to obtain information from third parties and other sources; protect the privacy of third parties; and safeguard classified information.

Aside from the specific protections afforded classified information, USAID must also protect the names of organizations and individuals within any classified systems associated with the PVS that mistakenly become recompiled into the non-classified USAID system. Nondisclosure of this information protects the government's operational counterterrorism and counterintelligence missions, as well as the personal safety of those involved in counterterrorism investigations.

B. Summary of the Final Rule

The final rule issued by USAID generally exempts portions of the PVS which qualify from:

- Accounting of Certain Disclosures.
- Access to Records.
- Agency Maintenance, Collection, and Notification Requirements.
- Agency Rulemaking Requirements Relating to Notification, Accounting, and Access.
- Civil Remedies.
- Right of Legal Guardians.

These exemptions are necessary to insure the proper functioning of the law enforcement activity, to protect confidential sources of information, to fulfill promises of confidentiality, to maintain integrity of the law enforcement procedures, to avoid premature disclosure of the knowledge of criminal activity and the evidentiary

basis of possible enforcement actions, to prevent interference with law enforcement proceedings, to avoid the disclosure of investigative techniques, to avoid endangering law enforcement personnel, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information, to avoid endangering these sources, and to facilitate proper selection or continuance of the best applicants or persons for a given position or contract. Although USAID is not a law enforcement or intelligence agency, the mandate to ensure USAID funding is not purposefully or inadvertently used to provide support to entities or individuals deemed to be a risk to national security necessarily requires coordination with law enforcement and intelligence agencies as well as use of their information. Use of these agencies' information necessitates the conveyance of these other systems' exemptions to protect the information as stated.

The final rule issued by USAID specifically exempts portions of the PVS which qualify from:

- Accounting of Certain Disclosures.
- Access to Records.
- Agency Maintenance, Collection, and Notification Requirements.
- Agency Rulemaking Requirements Relating to Notification, Accounting, and Access.

These exemptions are claimed to protect the materials required by executive order to be kept secret in the interest of national defense or foreign policy, to prevent subjects of investigation from frustrating the investigatory process, to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information, to avoid endangering these sources, and to facilitate proper selection or continuance of the best applicants or persons for a given position or contract.

C. Rulemaking History

On July 20, 2007, USAID published a proposed rule in the **Federal Register** (72 FR 39769) exempting portions of the PVS which originate with government departments and agencies other than USAID from sections of the Privacy Act of 1974. Interested individuals were given 60 days to comment on the proposed rule. During the 60-day comment period, USAID received more than 175 comments from respondents.

The respondents included NGOs, academic institutions, private companies, public interest groups, and interested individuals.

This final rule amends 22 CFR 215.13 and 215.14 to exempt the PVS from certain requirements under the Privacy Act. Prior to issuing this final rule, USAID has carefully considered program requirements, respondent comments, and national security and foreign policy impacts.

D. Discussion of Comments

Demonstrated Need for PVS

Many of the organizations that submitted comments suggested that since there is no evidence that USAID funds are flowing to terrorist organizations through NGOs, there is no need for a vetting system. Support for this proposition was based, in part, on the assertion that the Office of Inspector General (OIG) at USAID, in its Semi-Annual Reports to Congress on USAID's program for West Bank and Gaza, has stated that there has been no finding of terrorist organizations receiving USAID funds under that program. USAID notes, however, that in its November 6, 2007 audit report of USAID's anti-terrorism vetting procedures, the OIG recommended that USAID should develop and implement a worldwide anti-terrorism vetting program to include both U.S. and non-U.S.-based partners.

USAID is the Executive Branch agency primarily responsible for implementing the bilateral foreign assistance program of the United States. USAID relies heavily upon U.S. and foreign NGOs in implementing international assistance, education and other programs in furtherance of U.S. foreign policy, humanitarian, international relations, and national security interests and objectives.

Consistent with applicable law and agency policy, USAID has taken a number of steps, when implementing the U.S. foreign assistance program, to help ensure that agency funds and other resources do not inadvertently benefit individuals or entities that are terrorists, supporters of terrorists or affiliated with terrorists. Specifically, USAID has taken the actions described below.

In March 2002, USAID issued Acquisition and Assistance Policy Directive (AAPD) 02-04. AAPD 02-04 required all USAID solicitations and contracts, Annual Program Statements or Requests for Applications and grants or cooperative agreements, or other comparable documents issued by USAID to contain a clause reminding the Agency's contractor and grantee

partners of U.S. Executive Orders (such as Executive Order 13224) and U.S. law prohibiting transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. This requirement subsequently has been incorporated into USAID's Automated Directives System (ADS).

In December 2002, USAID issued AAPD 02-19 (as revised, now AAPD 04-14), which requires USAID agreement officers to obtain a terrorist financing certification from both U.S. and non-U.S. NGOs before the NGO would be eligible to receive an award of a grant or cooperative agreement. The purpose of the certification is to provide USAID with assurances that it is not entering into an assistance agreement with an organization that provides or has provided assistance to terrorists or for terrorist activity.

In November 2005, USAID issued Procurement Executive's Bulletin No. 2005-12, reminding contracting officers and agreement officers of their responsibilities to perform due diligence in ensuring that organizations receiving contracts, grants and cooperative agreements are eligible for these awards in accordance with Federal statutes and policy. Among other things, that Bulletin reminds contracting officers and agreement officers of their responsibility, before making an award, of checking the master list of specially designated nationals and blocked persons maintained by the Office of Foreign Assets Control (OFAC) within the U.S. Department of the Treasury.

USAID recognizes, however, that merely checking names against the OFAC master list and requiring self-certification may not constitute adequate due diligence in certain situations. In its terrorist financing certification, USAID discusses the need for applicants for USAID funds also to check the list maintained by the United Nations' 1267 Committee, the need to take into account their own knowledge and the need to take into account relevant public information that is reasonably available. Similarly, in the U.S. Department of the Treasury Anti-Terrorist Financing Guidelines: Voluntary Best Practices for U.S.-Based Charities, it is noted that, "while the [OFAC-maintained] List is a critically important compliance tool that can assist charities in meeting their legal obligations under the variety of sanctions programs that OFAC administers, it should only form one part of a charitable organization's broader risk-based approach to protect against the risks of terrorist abuse."

Accordingly, to complement its requirements for terrorist financing clauses, terrorist financing certifications, and review of public lists of designated groups and individuals, USAID proposes implementation of the PVS. The decision as to whether to implement PVS will be made by the incoming Obama Administration.

There have been allegations in the media and within the Executive and Legislative Branches that USAID funds may have gone (i) to organizations in West Bank and Gaza which are controlled by Hamas or which otherwise have ties to terrorist groups, (ii) to an organization in Pakistan controlled by an individual who was indicted based on alleged ties with terrorists, and (iii) to an organization in Bosnia controlled by an individual about whom derogatory information was reported. Although none of these grant activities resulted in assistance being furnished directly to a designated individual or entity, USAID believes that the development of a comprehensive, systematic, and automated vetting system is essential to ensuring that funds or other resources provided in the future are not diverted to the control of terrorists or terrorist organizations.

Moreover, whether or not any of the allegations referred to above had a valid basis in fact, USAID does not believe that it should wait for hard proof that our funds are actually flowing to terrorists before implementing additional safeguards to its anti-terrorism financing program—even the suggestion that our funds or resources are benefiting terrorists is harmful to U.S. foreign policy and U.S. national interests.

Vetting conducted since 2001 for the USAID West Bank and Gaza Mission has already proven effective in preventing USAID funds and materials from flowing to foreign terrorist organizations or groups or individuals associated with such organizations. Individuals involved in or otherwise associated with terrorism have been specifically identified through the West Bank and Gaza vetting process. Without vetting, USAID funds or materials could have inadvertently been given to these individuals or groups. In light of the fact that the statutorily required vetting currently being carried out for our West Bank and Gaza programs has uncovered derogatory information on some of the applicants for USAID funds and materials, a more comprehensive, systematic, and automated vetting process unquestionably will improve the Agency's due diligence and will result in more effective methods to help minimize the risk that USAID funds will

be diverted to terrorists or for terrorist purposes.

Statutory Basis for PVS

Some organizations suggested that, with the exception of USAID programs in West Bank and Gaza, there is no basis in statute or Executive Order justifying implementation of PVS.

The Foreign Assistance Act of 1961, as amended (the "FAA"), provides the President with broad discretion to set terms and conditions in the area of foreign policy. Specifically, numerous sections of the FAA authorize the President to furnish foreign assistance "on such terms and conditions as he may determine". See, e.g., section 122 of the FAA, which provides that, "[i]n order to carry out the purposes of this chapter [i.e., development assistance], the President is authorized to furnish assistance, on such terms and conditions as he may determine, to countries and areas through programs of grant and loan assistance, bilaterally or through regional, multilateral, or private entities." Similarly, sections 103 through 106 of the FAA authorize the President to furnish assistance, on such terms and conditions as he may determine, for agriculture, rural development and nutrition; for population and health (including assistance to combat HIV/AIDS); for education and human resources development; and for energy, private voluntary organizations, and selected development activities, respectively. The FAA also authorizes the President to "make loans, advances, and grants to, make and perform agreements and contracts with, any individual, corporation, or other body of persons, friendly government or government agency, whether within or without the United States and international organizations in furtherance of the purposes and within the limitations of this Act."

These authorities have been delegated from the President to the Secretary of State and, pursuant to State Department Delegation of Authority 293, from the Secretary of State to the Administrator of USAID. Agency delegations of authority, in turn, delegate these authorities from the Administrator to Assistant Administrators, office directors, Mission Directors, and other Agency officials.

In providing foreign assistance, the Administrator must take into account relevant legal restrictions. For example, the FAA requires that all reasonable steps be taken to ensure that assistance is not provided to or through individuals who have been or are illicit narcotics traffickers. Pursuant to annual

foreign operations appropriations acts, assistance to foreign security forces requires vetting to ensure that assistance is not provided to units where there is credible evidence that the unit committed gross violations of human rights. These vetting requirements now have been incorporated into the FAA. Restrictions in the FAA against supporting terrorism or providing assistance to terrorist states, as well as restrictions in Title 18 of the United States Code on the provision of support or resources to terrorists, similarly support a decision by the Administrator of USAID to authorize terrorist screening procedures.

In addition, the broad authority of the FAA permits the Administrator of USAID to consider a range of foreign policy and national security interests in determining how to provide foreign assistance. The United States has a strong foreign policy and national security interest in ensuring that U.S. assistance is not provided to or through individuals or organizations that have links to terrorists. This interest arises both because of our concern about the potential diversion of U.S. assistance to other uses and also our interest in ensuring that terrorist individuals and groups do not garner the benefit of being the distributor of U.S. assistance to needy recipients in foreign countries. The United States is an advocate of strong anti-terrorism provisions and has urged other nations to control the flow of funds and support to terrorists. There could be significant negative foreign policy repercussions if it were determined that the United States was funding individuals and organizations with ties to terrorists.

Further, Homeland Security Presidential Directive/HSPD-6 states that to protect against terrorism it is the policy of the United States to (1) develop, integrate, and maintain thorough, accurate, and current information about individuals known or appropriately suspected to be or have been engaged in conduct constituting, in preparation for, in aid of, or related to terrorism, and (2) use that information as appropriate and to the full extent permitted by law to support Federal screening processes. HSPD-6 also requires the heads of executive departments and agencies to conduct screening using Terrorist Information (as defined therein) at all appropriate opportunities. In accordance with HSPD-11, USAID has identified NGO applications for USAID funds as one of the opportunities for which screening could be conducted. Accordingly, use by USAID of information contained in

USG terrorist databases, *i.e.*, vetting, is entirely consistent with HSPD-6.

Finally, legislative and Executive Order prohibitions against furnishing financial or other support to terrorists or for terrorist related purposes, or against engaging in transactions with individuals or entities that engage in terrorist acts, provide justification not to award assistance if USAID already has access to information showing that the applicant for assistance is involved in terrorism. Some of these prohibitions can be found in Sections 2339A and 2339B of Title 18 of the United States Code, Executive Order 12947, as amended by Executive Order 13099, Executive Order 13224, and Title VIII of the USA Patriot Act. Accordingly, USAID's authority to conduct vetting is implied from these authorities since, to avoid violation of the authorities, USAID must use some sort of screening.

Based upon all of the above, USAID has concluded that it does indeed have the legal authority to implement the PVS.

Related comments suggested that USAID could not implement PVS without first obtaining a deviation from the Office of Management and Budget (OMB) in accordance with OMB Circular A-110 and USAID Regulation 226 (22 CFR 226). OMB Circular A-110 governs the administration of grants and cooperative agreements to institutions of higher education, hospitals, and other non-profit organizations. USAID Regulation 226 implements OMB Circular A-110. 22 CFR 226.1 provides that USAID will not "impose additional or inconsistent requirements, except [through a deviation granted by OMB] * * *, or unless specifically required by Federal statute or executive order."

USAID has reviewed the comments regarding Regulation 226 and has concluded that a deviation from OMB is not required. USAID has the freedom to make suitability determinations regarding applicants for grants and the use of PVS is part of the suitability determination process. Furthermore, the Partner Information Form, published in the **Federal Register** on October 2, 2007, and approved by OMB on August 19, 2008, complies with 5 CFR 1320, OMB's regulations on controlling paperwork burdens on the public, as required by 22 CFR 226.12, USAID's regulatory provision requiring compliance with OMB, and supplements the Standard Form 424 series.

Burden on Applicants

The most frequent concern expressed in the comments received was that providing information to USAID would create an undue burden on

organizations applying for U.S. funds in terms of non-programmatic costs and person hours. Organizations submitting comments feared that detailed personal information would have to be collected from every director, board member, officer and employee of an applicant, in addition to information collected from similar personnel of sub-recipients. Concerns also were expressed about the burden placed on USAID personnel who will receive and process the information provided.

It is contemplated that if the incoming Obama Administration approves implementation of PVS, it will be rolled out in an orderly fashion, with initial implementation for approximately four programs worldwide. While USAID believes that its Paperwork Reduction Act estimate of the burden of the proposed collection of information for PVS is accurate, USAID would continue to monitor implementation of PVS if it is implemented to determine what the burden on applicants actually will be and to determine what operation of PVS will cost USAID in terms of dollars and in terms of personnel hours.

NGO partners can be assured that USAID has no intention to vet hundreds or thousands of employees for each acquisition or assistance action. Review of Mission Order No. 21, issued by USAID's Mission for West Bank and Gaza to describe the Mission's current terrorist financing procedures, and the recently approved Partner Information Form, are instructive in this regard.

Under the definition of "key individuals," Mission Order No. 21 lists only "principal" officers of an organization's governing body and only "principal" officers of an organization, as opposed to all of these officers. The Mission reports that during the first ten months that the Mission utilized a database vetting system similar to that proposed under PVS, vetting was conducted only on an average of approximately 3.2 key individuals per organization. Based on the Mission's experience during that time period, a typical organization would submit information on 4 to 6 key individuals, with the high range being 10 to 14 and the low range (for sole proprietorships or simple two-person partnerships) being 1 to 2 persons. Moreover, under those screening procedures, the initial determination as to who would be considered a "key individual" for a particular activity, and thus will require vetting, is left to the organization applying for funds. After receiving the information, the Mission then may request clarification or, if appropriate, go back to an organization to seek information on additional individuals.

The Partner Information Form also includes a section of instructions to ensure that applicants are accurately filling out the form and are not over-reporting information that is unnecessary. The form includes a definition of "key individuals" that is similar to the definition contained in West Bank and Gaza Mission Order No. 21. It is expected that the numbers of key individuals selected for vetting under programs identified for initial PVS implementation will be comparable to the numbers cited above for West Bank and Gaza program.

USAID does recognize that including more complex and sophisticated U.S. organizations into this mix may well result in higher numbers and of course this will be carefully monitored during the early phases of PVS implementation should PVS be approved for implementation by the incoming Obama Administration.

USAID's NGO partners also commented that individuals who serve on the boards of NGOs typically are distinguished and prominent individuals who serve without remuneration as a public service. In addition, many NGOs also deploy volunteers. Concerns were expressed over the adverse effect that the proposed PVS screening might have on these prominent board members or on NGO volunteers. Based on the West Bank and Gaza procedures described above, however, it may well be that neither the NGO applicant nor USAID will consider these prominent board members or these volunteers as the type of individual necessary to include in the screening process.

USAID currently is developing guidance and protocol for the initial implementation of PVS, if approved, and the Agency will monitor the accompanying administrative burden on our partners and on our staff throughout the process. In the development of this information, USAID is taking into consideration experience, expertise and results that the Mission for West Bank and Gaza has obtained through more than six years of vetting. Once the guidance and protocol have been developed, the Agency will share it with our NGO partners and also provide appropriate training for affected applicant organizations.

Privacy Act and Due Process Requirements

Comments received by USAID expressed concern that implementation of PVS would result in the creation of files or databases of innocent people not suspected of a crime and that sharing of information between USAID and other

agencies not authorized to view private information would violate the Privacy Act. Concern also was expressed that individuals and organizations would not know their status in the PVS since one of USAID's **Federal Register** notices states that USAID will not confirm or deny that an individual "passed" or "failed" screening. Comments received asserted that this lack of due process would result in loss of employment and/or award of funds without effective recourse. Finally, at least one organization asserted that European based NGOs might have problems complying with PVS due to European data protection regulations.

Throughout the design process of PVS, USAID has been committed to protecting national security while complying with all administrative requirements, and protecting all privacy, civil liberty and other rights of its NGO partners and their employees. In that regard, the July 17, 2007 System of Records Notice for the PVS does include an appropriate routine use allowed for under the Privacy Act, permitting the sharing of information, provided to USAID by applicants, with the intelligence community for the purposes of vetting following the processes established by the PVS.

Information provided to USAID by applicants will be transmitted to USAID employees who will check that information against one or more databases maintained by the intelligence community. Once checked, the information provided by NGO partners will be maintained in secure files, as detailed in the **Federal Register** notices, by and at USAID. Consistent with the Privacy Act, all information submitted on individuals and maintained in the USAID system will be available for those individuals to request, review and correct. Intelligence community systems will not retain information on individuals where there is no match.

USAID will not deny an application merely because there is an "encounter" or positive match between information provided by an applicant and information maintained in a terrorism database. Instead, USAID will "look behind" that match, considering the accuracy and severity of the information, the reliability of the source, corroboration, and other pertinent matters before any decision is made regarding an award. This review will include assessment of the terrorist information available in relevant databases, consideration of information provided by USAID Missions or U.S. Embassies and any other relevant information available to the Agency.

USAID has been working closely with the Department of Justice to ensure that due process rights are incorporated into PVS. Any decision communicated to an applicant that award will not be made as a result of PVS screening will be accompanied by a reason for such denial. Further, opportunity for review of that decision will be afforded to the denied applicant. The statement in USAID's rulemaking notice that USAID will not "confirm or deny that an individual 'passed' or 'failed' screening" only pertains to the fact that USAID has not been authorized to confirm information maintained in terrorist screening databases. This is to protect the classified nature of information maintained by the intelligence community, preclude frustration of the investigative process, avoid disclosure of investigative techniques, and for other reasons specified in our rulemaking notice. Since, as stated above, USAID award decisions will not be based simply on a "match" between information provided to USAID by an applicant and information already contained in a terrorism database, refusal to acknowledge whether or not there was a match should be of no consequence for purposes of implementation of PVS.

One European based agency expressed concerns to the effect that compliance with PVS requirements by our European partners could result in violation of EU privacy laws. More specifically, the European based agency suggested that article 25 of EU Directive 95/46/EC on Data Protection, designed to protect the privacy rights of NGO employees and other individuals, might prohibit transfer to USAID of the information requested under PVS. This is because the "EU data protection authorities do not generally regard the United States as ensuring adequate protection for personal data since the United States does not have data privacy laws similar to the European regime." The European based agency also suggested that article 7 of the EU Directive might pose problems for compliance with PVS requirements. That article prohibits the disclosure or other processing of personal data except where disclosure is necessary for compliance with a legal obligation or in other limited circumstances. Support for this proposition is based on the SWIFT opinion issued by EU data protection authorities.

USAID has conducted a preliminary legal review of these concerns. The Agency does not believe that PVS requirements violate article 7 of the EU Directive since the information proposed to be provided to USAID is

necessary for USAID to further legitimate U.S. interests, i.e., ensuring that U.S. funds are not diverted to terrorists or used for terrorist purposes. Pursuit of legitimate interests is one of the stated exceptions to the prohibition contained in article 7. USAID also does not believe that fundamental rights or freedoms of the data subjects will be compromised through compliance with PVS. In this regard, USAID does not believe that the facts in the SWIFT opinion are relevant to the national security screening procedures contemplated under PVS. In SWIFT, financial information was collected and then transferred to U.S. intelligence and such transfer was accomplished without notifying the affected individuals. Neither of those actions is contemplated by PVS.

Similarly, USAID does not believe that article 25 of the EU Directive will be violated as PVS is being designed to provide more than "an adequate level of protection." For more information on this point, see the response to data security and other related concerns in this final rule. In any event, USAID is not inclined to ease or otherwise dilute its information requirements because European data protection authorities possibly might view PVS as a system that will not adequately protect information provided.

Consultation With Partners

A number of organizations expressed concern over the lack of prior consultation between USAID and its traditional implementing partners. In particular, (i) the timing of the publication of the PVS notices in the **Federal Register** (mid-July) and (ii) the statement in the Privacy Act System of Records notice that the new system of records would become effective on the same date that comments on that notice were due have generated questions about USAID's willingness to effectively and transparently engage the NGO community in a dialogue on PVS.

Administrative regulations prevented USAID from discussing specifics of the proposed PVS prior to publication of the **Federal Register** notices. However, to remedy this perceived oversight in communication, USAID convened a number of outreach sessions with its NGO partners. Moreover, USAID considered seriously all comments submitted by the NGOs in response to the four **Federal Register** notices, as reflected in this final rule. In any event, it should be pointed out that by no means did USAID "slip" notice of the proposed PVS into the **Federal Register** in mid-summer to avoid meaningful review and comment by the NGO

community. Publication of the PVS notices was approved by USAID leadership in April 2007. Following that decision, USAID staff engaged in consultations with OMB for several months, discussing both procedural and substantive aspects of the proposed PVS and the required notices. In addition, internal USAID procedures governing publication of notices in the **Federal Register** had to be followed, further delaying publication. It was not until July 2007 that all prerequisite steps for publication had been satisfied. Thus, publication at that time was merely the next logical step in the administrative process and not the result of any intention on the part of USAID to sneak these notices by a vacationing NGO community.

Similarly, the effective date selected for the PVS system of records does not reflect unwillingness on USAID's part to give serious consideration to and incorporate into the proposed PVS, as appropriate, comments submitted by the NGOs in response to the PVS notices.

The Privacy Act System of Records notice for PVS was published in the **Federal Register** for public comment on July 17, 2007. The notice provided that written comments must be received on or before August 27, 2007. The notice went on to state that unless there is further notice in the **Federal Register**, the new system of records would become effective on August 27, 2007. This did not mean that USAID would not review comments or that USAID would not take these comments into account as decisions were being made on whether to or how to implement the PVS.

USAID was required to select a date to insert in the System of Records Notice at which time the system of records would become effective. Effectiveness of the PVS system of records on August 27, 2007 in no way indicated that the proposed PVS was approved on that date, that it became operational on that date, or that comments received in response to any of the four notices would be ignored. As demonstrated by USAID subsequent to the August 27, 2007 date, the Agency has been ready, willing and able to continue the dialogue with the NGOs and to ensure that approval of PVS only would be granted once the recommendations, concerns and comments of the NGOs have fully been reviewed and considered by USAID.

As previously indicated, on October 2, 2007, USAID published a fourth notice in the **Federal Register**. That notice, issued pursuant to the Paperwork Reduction Act, republished and amended the notice previously

published by USAID on July 23, 2007, and contains the proposed Partner Information Form, which will be used during the pilot phase of PVS. The form was developed with guidance from the USAID Mission in West Bank and Gaza, in response to recommendations made by the GAO and in compliance with all administrative approvals and with requirements set by the intelligence community. Comments on this fourth notice were due on or before December 3, 2007, and the Partner Information Form was approved by OMB on August 19, 2008. All comments received in response to this fourth notice have been taken into account by USAID.

Risk to Partners

Some organizations claimed in their comments that there were considerable dangers associated with USAID using its implementing partners for U.S. law enforcement or intelligence purposes in foreign countries and that this could lead to retaliation by foreign governments against partner employees and employees of subs of partners.

First of all, PVS is not, and should not be characterized as, a system in which USAID implementing partners will be acting as agents for U.S. law enforcement or intelligence activities. Rather, PVS simply is an additional mechanism for USAID to use in determining the eligibility of organizations applying for U.S. funds. Such applicants already provide information to USAID on its management personnel and on key employees as part of the application and evaluation process. PVS merely requires applicants to provide additional information in that process. In no way should this exercise be viewed as law enforcement or intelligence gathering.

Further, as previously communicated to the NGO community, one of the purposes of PVS is to enhance the safety overseas of both USAID personnel and officials and employees of USAID's partners. Ensuring that principal individuals, officers, directors or other employees are not associated with terrorists or terrorism, where such individuals will be working with USAID Missions and will be implementing USAID foreign assistance activities alongside other partner employees, can only improve safety and reduce the risk of kidnapping, assassination or injury.

Public Comment Period

Concerns were expressed that the time periods made available for public comment did not afford the NGO community adequate time to prepare comments or for USAID to carefully consider and respond to these

comments. It also was asserted that OMB regulations require USAID to provide between 60 and 90 days for comment. Consequently, NGOs have requested extension of the comment periods.

USAID has followed all administrative requirements and provided a full 40-day comment period for the system of records notice, a full 60-day comment period for the proposed rule, and a full 60-day comment period for both the original and amended information collection notices. All time limits are set by the Privacy Act and the Paperwork Reduction Act and no deviations to those time limits were requested by USAID.

In any event, USAID did express its willingness to maintain a dialogue with the NGO community and with interested Congressional committee staff on PVS and associated notices. Expiration of the stated time periods for our public notices did not dictate when PVS will be put into operation.

Procedural Specifics

Some comments received expressed concern over the lack of specifics with respect to PVS procedures. For example, questions were raised over the type and extent of information to be requested by USAID, which people will be screened, and how long information provided to USAID will be retained. The perceived lack of procedural specifics also resulted in fears that USAID would compile a secret blacklist of ineligible grant applicants, that individuals whose identifying data match data in an intelligence community database will not be told of the source of this match and that NGO applicants will be unable to appeal or dispute denials of their applications for funding.

While some of the procedures attendant to PVS already have been agreed upon, other procedures remain to be developed as part of the Agency's guidance and protocol development process. For example, as stated in the system of records notice published in the **Federal Register**, a retention and disposition schedule will need to be developed for PVS. Currently, in West Bank and Gaza, required information is submitted by applicants via paper. However, USAID's Office of Security is working with a contractor to design a secure portal to permit applicants to submit data electronically. With respect to retention of records generated under PVS, it is likely that the same rules applicable to documents submitted to the U.S. Government under acquisition and assistance activities will be made applicable to information submitted

under PVS. In any event, should implementation of PVS be approved by the incoming Obama Administration, all these procedures would be fleshed out during the guidance policy and protocol development process leading up to the initiation of PVS and then adjusted as USAID gathers information and experience.

Once specific procedures for PVS have been agreed upon, they will be published by USAID in its ADS and, as appropriate, in applicable regulation. Current operation of vetting and other related procedures in West Bank and Gaza can be found in Mission Order No. 21 and may provide a solid basis for the proposed implementation of PVS for other programs.

USAID will not maintain in its files any information other than information provided by applicants, maintained in the USAID PVS system of records, and information that constitutes related administrative records. Screening of an organization will consist of a review of potential derogatory information regarding principal individuals of the organization or the organization itself. Results of this screening will be recorded to document actions taken concerning the award for which the organization was screened. Results will not be utilized to create lists of organizations which would then be used for subsequent screening, which is what is suggested by allegations that there will be a secret blacklist. Instead, whether an organization is being screened for the first time or whether screening is being conducted at subsequent dates, screening will be conducted through the same original process.

Moreover, as previously indicated, award decisions will not be based simply on whether there has been a match with respect to one or more principal individuals of an organization and information contained in a terrorism database. Instead, USAID will review the intelligence behind the match. This review will include consideration of the severity of the information, the reliability of the source, corroboration, if any, etc. As previously stated, USAID cannot confirm or deny a person's appearance in a terrorism database. Nevertheless, any denial of funding by USAID as a result of PVS screening will be accompanied by a reason for that denial and an opportunity for the organization to appeal administratively. The amount of information provided to a denied applicant will be dependent on the sensitivity of the information, *i.e.*, whether some or all of the information is classified and, if so, how much of that

information can be released without compromising investigative or operational interests.

Unconstitutionally Vague

It was asserted in some of the comments received that USAID's description of the purpose of the proposed PVS in the **Federal Register** notices, *i.e.*, to ensure that neither USAID funds nor USAID-funded activities inadvertently or otherwise provide support to entities or individuals "associated with terrorism," was Constitutionally vague. In support of this position, reference was made to *Humanitarian Law Project v. Treasury*, a case decided in the Central District of California in November 2006. In that decision, provisions of Executive Order 13224 referencing people and groups "otherwise associated" with terrorism were held to be impermissibly vague.

It should be noted that in April 2007, the *Humanitarian Law Project* court granted the U.S. Government's motion for reconsideration. The court ruled that the regulation issued by the OFAC defining the "otherwise associated with" provision of Executive Order 13224 remedied the provision's "Constitutional defects". In addition, the court also vacated its order and decision finding that the President's designation authority under Executive Order 13224 was unconstitutionally vague and overbroad.

It also should be noted that violations of OFAC-administered economic sanctions activities may result in imposition of civil fines and/or criminal penalties. PVS, on the other hand, is being designed to help determine whether applicants for USAID funds are responsible, suitable or otherwise eligible to receive these funds. The legal standards applicable to imposition of civil fines or criminal penalties for violation of sanctions differ substantially from the legal standards applicable to denial of Federal grants and other funding. Accordingly, analogies between the *Humanitarian Law Project* case and the proposed PVS are misplaced.

While the development of a static template which listed all applicable criteria or a point scoring system which would scientifically identify individuals and entities "associated with terrorism" may be preferred, such an approach, if even feasible, would prove to be an inefficient and ineffective way to address the issue of funds or other support flowing to terrorists or terrorist organizations or for terrorist activities. USAID needs to have the ability to be flexible in its analysis so that the Agency can adapt to the range of

activities and the range of circumstances surrounding implementation of the U.S. foreign assistance program. The proposed PVS includes a process where all data available to USAID on applicants will be reviewed at various levels within the Agency. This information will be checked for accuracy, relevance, timeliness, reliability, etc. Foreign policy and other related views of the country team also can be taken account. In addition, USAID has been working closely with the Department of Justice to ensure that due process and other relevant legal rights are incorporated into the design and implementation of PVS.

Based upon all of the above, USAID believes that PVS meets all applicable legal standards.

Data Security

Concern was expressed over the security of records maintained by USAID under PVS, particularly in overseas locations. An example provided was GAO criticism of the security of information held in West Bank and Gaza. Concern also was expressed about who would have access to data maintained in PVS. Specifically, questions were raised about the propriety of "authorized" USAID contractors having access to the data involving other contractors and involving all grantees.

In response to vetting database weaknesses identified by both the GAO and OIG, the Mission for West Bank and Gaza has incorporated a number of improvements in its system. For example, vetting reports that previously had been held in an unlocked file cabinet now are stored in secure, locked cabinets. The Mission also has developed user requirements, system architecture, data dictionaries, and user manuals for its vetting system. PVS will, of course, take advantage of all these improved methods.

On an Agency-wide basis, USAID's information security program is considered to be exceptional. USAID is required to report annually on Federal Information Security Act compliance, both to OMB and to the House of Representatives. Additionally, the program is audited by the USAID OIG. The House Oversight and Government Reform committee issues each year a governmentwide scorecard rating all agencies. For each of the past four years, USAID has been rated at the A+ level.

In structuring USAID's "award winning" computer security program, the Office of the Chief Information Officer has deployed a very robust and sophisticated set of technical defenses on USAID's network. In addition,

USAID has a very strong security awareness training program.

The PVS system will be housed in USAID headquarters in Washington, DC, within the Agency's firewall and on USAID servers. When an authorized user of PVS accesses the application through the USAID intranet, the user's network credentials will be authenticated. PVS will limit the user's capability to view personally identifiable data and operate the system based on the user's roles configured within the system. Policy will dictate that each user will be assigned only those roles required to perform his or her job function within the system. All personally identifiable information will be protected in accordance with the Privacy Act.

Specific retention and disposition instructions will be formulated by USAID at a later date as policy makers are better informed by the proposed pilot for PVS. Typical disposition instructions for electronic data include archiving and later destruction, as well as specified periods of time for such actions.

Evidence of Effectiveness

One organization indicated that its objections to PVS are based on its research and advocacy relating to charities and counterterrorism programs. The organization stated that it had found that similar programs tended to create barriers to effective delivery of aid programs, to discourage small NGO application for grants, and to alienate international partners. However, the organization did not provide any data or other information to support its claims.

USAID recognizes that any additional requirement (whether PVS related or otherwise) will affect the delivery of assistance. The goal of USAID is to achieve the purpose behind any new requirement in the most efficient manner that will minimize any potential negative impact on implementation of activities. In the experience of USAID's Mission in West Bank and Gaza, the most significant negative impact of vetting over the past five years or so has been delay. Vetting conducted manually with limited dedicated resources resulted in backlogs well in excess of 3,500 names. Delays in processing these vetting requests clearly caused significant barriers to effective delivery of aid. This, however, further underlines the need to have a comprehensive, systematic and automated system for vetting requests to be processed formally and electronically, rather than on an ad-hoc basis. Under such a program, it is expected that delays encountered by the Mission in West

Bank and Gaza will significantly be reduced during implementation of PVS for subsequent programs.

The suggestion that small NGOs are discouraged from applying for grants seems to be based on anecdotal evidence. USAID's experience in the West Bank and Gaza can neither confirm nor deny this hypothesis as data is not collected on number of potential partners that may abstain from applying for assistance. The Mission for West Bank and Gaza does, however, provide assistance to a large number of small NGOs and those NGOs are indeed vetted. To the extent that some small NGOs may be apprehensive about vetting, it is hoped that the transparency, public information and education, and comment periods surrounding the PVS public notice process will provide assurances about the uses of the system and its safeguards, and help dispel any extreme rumors about the system.

The same response largely is applicable to the situation with international partners. Concerns raised by international partners in the West Bank and Gaza may reflect the uniqueness of vetting to that program. International partners not accustomed to working in countries or programs where PVS may be implemented may be less comfortable than partners that have worked in those countries or with those programs for years. If PVS is implemented, such apprehensions should subside.

Inaccuracies and Errors

Comments received suggest that government watch lists are inaccurate. Recently, the Department of Justice's Inspector General reported that these lists continue "to have significant weaknesses," producing a high error rate and a slow response to complaints from citizens. Since PVS proposes to utilize such terrorism databases, concerns have been expressed that USAID vetting will generate numerous "false positives."

Although the watch list error rate actually is quite low, the intelligence community continues to seek improvement in the terrorist screening process. While the intelligence community will continue to observe all privacy rules and policies, it also seeks to improve its information technology capabilities by researching and developing the latest computerized name-matching programs to ensure the highest watch list data quality. In fact, in an October 2007 report on Terrorist Watch List Screening, the GAO recommended that the intelligence community prepare plans to facilitate

expanded and enhanced use of the watch list.

In any event, decisions by USAID under PVS as to whether or not to award funds to applicants will not be based on the mere fact that there is a "match" between information provided by an applicant and information contained in these terrorism databases. Rather, USAID will determine whether any such match is valid or is a false positive. The detailed identifying information required of applicants under the PVS will help minimize instances of individuals being misidentified.

Lack of Office of Management and Budget (OMB) Involvement

Some comments suggested that clearance or other involvement of OMB in the PVS process was not obtained by USAID. More specifically, it was asserted that USAID overlooked its responsibilities under Executive Order 12866 concerning the determination that PVS is not a "significant" regulatory action.

As required by OMB Circular A-130, USAID provided appropriate materials (cover letter, system of records notice, proposed rule) to OMB as well as to the Senate Committee on Homeland Security and Government Affairs and the House Committee on Government Reform. The proposed rule contained a statement that USAID had determined that it was not a significant regulatory action and, therefore, is not subject to review under Executive Order 12866. OMB agreed with this determination, and cleared the proposed rule for publication in the **Federal Register**. OMB continues to view this rule as not a significant regulatory action. Consistent with the requirements of the Congressional Review Act, USAID is submitting this final rule to each house of Congress and to OMB. This submittal includes USAID's determination that it is not a major rule. USAID has kept OMB apprised of the procedures being followed to establish PVS and has engaged in consultations with OMB prior to the publication of the notices in the **Federal Register**, during the comment periods, and after the comment periods closed. Where clearance from OMB is required, USAID is complying with these clearance requirements by consulting with OMB as necessary.

E. Impact Assessment

Regulatory Planning and Review

This is not a significant regulatory action and, therefore, is not 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.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), USAID has considered the economic impact of the rule and has determined that its provisions would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act does apply because the proposed changes impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3601 *et seq.*

Lists of Subjects in 22 CFR Part 215

Freedom of Information, Investigations, Privacy.

Regulatory Text

■ For the reasons stated in the preamble, USAID amends 22 CFR part 215 as follows:

PART 215—REGULATIONS FOR IMPLEMENTATION OF PRIVACY ACT OF 1974

■ 1. The authority citation for 22 CFR part 215 is revised to read as follows:

Authority: Public Law 93-579, 88 Stat. 1896 (5 U.S.C. 553, (b), (c), and (e))

■ 2. Amend § 215.13 by adding paragraph (c)(2) to read as follows:

§ 215.13 General exemptions.

* * * * *

(c) * * *

(2) *Partner Vetting System*. This system is exempt from sections (c)(3) and (4); (d); (e)(1), (2), and (3); (e)(4)(G), (H), and (I); (e)(5) and (8); (f), (g), and (h) of 5 U.S.C. 552a. These exemptions are necessary to insure the proper functioning of the law enforcement activity, to protect confidential sources of information, to fulfill promises of confidentiality, to maintain the integrity of law enforcement procedures, to avoid premature disclosure of the knowledge of criminal activity and the evidentiary basis of possible enforcement actions, to prevent interference with law enforcement proceeding, to avoid the disclosure of investigative techniques, to avoid endangering law enforcement personnel, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information, to avoid endangering these sources, and to

facilitate proper selection or continuance of the best applicants or persons for a given position or contract. Although the primary functions of USAID are not of a law enforcement nature, the mandate to ensure USAID funding is not purposefully or inadvertently used to provide support to entities or individuals deemed to be a risk to national security necessarily requires coordination with law enforcement and intelligence agencies as well as use of their information. Use of these agencies' information necessitates the conveyance of these other systems exemptions to protect the information as stated.

■ 3. Amend § 215.14 by adding the heading "Note to paragraph (c)(5)" to the undesignated text at the end of the section and paragraph (c)(6) to read as follows:

§ 215.14 Specific exemptions.

* * * * *

(c) * * *

(6) *Partner Vetting System.* This system is exempt under 5 U.S.C. 552a (k)(1), (k)(2), and (k)(5) from the provision of 5 U.S.C. 552a (c)(3); (d); (e)(1); (e)(4)(G), (H), (I); and (f). These exemptions are claimed to protect the materials required by executive order to be kept secret in the interest of national defense or foreign policy, to prevent subjects of investigation from frustrating the investigatory process, to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques, to maintain the ability to obtain candid and necessary information, to fulfill commitments made to sources to protect the confidentiality of information, to avoid endangering these sources, and to facilitate proper selection or continuance of the best applicants or persons for a given position or contract.

Dated: December 23, 2008.

Randy T. Streufert,

Director, Office of Security.

[FR Doc. E8-31131 Filed 12-31-08; 8:45 am]

BILLING CODE 6116-01-P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2560

RIN 1210-AB24

Civil Penalties Under ERISA Section 502(c)(4)

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Final rule.

SUMMARY: This document contains a final regulation that establishes procedures relating to the assessment of civil penalties by the Department of Labor under section 502(c)(4) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). The regulation is necessary to reflect recent amendments to section 502(c)(4) by the Pension Protection Act of 2006, under which the Secretary of Labor is granted authority to assess civil penalties not to exceed \$1,000 per day for each violation of section 101(j), (k), or (l), or section 514(e)(3) of ERISA. The regulation will affect employee benefit plans, plan administrators and sponsors, fiduciaries, as well as participants, beneficiaries, employee representatives, and certain employers.

DATES: This final rule is effective on March 3, 2008.

FOR FURTHER INFORMATION CONTACT: Melissa R. Dennis, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693-8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

On August 17, 2006, the Pension Protection Act of 2006 (PPA), Public Law 109-280, 120 Stat. 780, amended title I of ERISA by adding or revising a substantial number of substantive provisions. In conjunction with many of these new or revised provisions, the PPA also amended the civil enforcement provisions in ERISA to provide the Secretary of Labor with authority to assess civil monetary penalties for violations of the substantive provisions.

Specifically, section 103(b)(1) of the PPA amended section 101 of ERISA by adding a new disclosure requirement under subsection (j), under which the plan administrator of a single-employer defined benefit pension plan must provide written notice of limitations on benefits and benefit accruals to participants and beneficiaries pursuant to section 206(g) of ERISA (or the parallel Internal Revenue Code provision at section 436(b)).¹ A notice of benefit limitations must be furnished within 30 days after a plan becomes subject to an ERISA section 206(g) funding-based restriction and at such other time as may be determined by the Secretary of the Treasury. Section 103(b)(2) of the PPA amended section 502(c)(4) of ERISA to provide the

Secretary of Labor with the authority to assess a civil penalty of not more than \$1,000 a day for each violation of ERISA section 101(j). The effective date of the provisions added by PPA section 103(b) is for plan years beginning on or after January 1, 2008.

Section 502(a)(1) of the PPA amended section 101 of ERISA by adding subsection (k), under which the plan administrator of a multiemployer pension plan must, upon written request, furnish certain documents to any plan participant, beneficiary, employee representative, or any employer that has an obligation to contribute to the plan. Section 502(a)(2) of the PPA amended section 502(c)(4) of ERISA to provide the Secretary of Labor with the authority to assess a civil penalty of not more than \$1,000 a day for each violation of ERISA section 101(k). The effective date of the provisions added by PPA section 502(a) is for plan years beginning on or after January 1, 2008.

Section 502(b)(1) of the PPA amended section 101 of ERISA by adding subsection (l), under which a plan sponsor or plan administrator of a multiemployer employee benefit plan must, upon written request, furnish to any employer with an obligation to contribute to such plan, notice of potential withdrawal liability. Section 502(b)(2) of the PPA amended section 502(c)(4) of ERISA to provide the Secretary of Labor with the authority to assess a civil penalty of not more than \$1,000 a day for each violation of ERISA section 101(l). The effective date of the provisions added by PPA section 502(b) is for plan years beginning on or after January 1, 2008.

Section 902(f)(1) of the PPA amended section 514 of ERISA by adding subsection (e)(3), under which the plan administrator of a plan with an automatic contribution arrangement shall provide to each participant, to whom the arrangement applies, notice of the participant's rights and obligations under such arrangement. Section 902(f)(2) of the PPA amended section 502(c)(4) of ERISA to provide the Secretary of Labor with the authority to assess a civil penalty of not more than \$1,000 a day for each violation of ERISA section 514(e)(3). The effective date of the provisions added by PPA section 902(f) is August 17, 2006.

On December 19, 2007, the Department published in the **Federal Register** a proposed rule to implement section 502(c)(4) of ERISA and invited interested parties to comment.² In

¹ Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713), the Secretary of the Treasury has interpretive jurisdiction over section 206(g) of ERISA.

² 72 FR 71842.

response to the proposal, the Department received two written comments representing plans and plan sponsors. Copies of the two comments are available under the "Public Comments" section of the Department's Web site at <http://www.dol.gov/ebsa>. After careful consideration of the issues raised in the written comments, the Department is publishing a final regulation, to be codified at 29 CFR 2560.502c-4, without change.

One commenter suggested that it may be premature to issue this civil penalty regulation in advance of substantive regulations under section 101(j), (k), or (l), or section 514(e)(3) of ERISA. As explained below, the civil penalty regulation being adopted herein is merely procedural in nature, *i.e.*, it establishes the process by which the Department may assess civil penalties and the process by which the respondent may challenge that assessment. If the Department or the Secretary of the Treasury were to issue regulations under section 101(j), (k), or (l), or section 514(e)(3) of ERISA, they would not likely have any impact on such procedures.³ Moreover, the Secretary's authority to assess civil penalties under this section is not conditioned on the existence of substantive regulations implementing section 101(j), (k), or (l), or section 514(e)(3) of ERISA. For these reasons, the Department does not believe it is premature to establish this civil penalty regulation at this time.

The commenters also asked whether the notice requirement in section 514(e)(3) of ERISA applies to plans with automatic contribution arrangements that are not intended to meet the requirements of the Department's regulation on qualified default investment alternatives, at 29 CFR 2550.404c-5. The notice requirement in section 514(e)(3) of ERISA applies only to automatic contribution arrangements described in section 514(e)(2) of ERISA. For purposes of section 514(e), section 514(e)(2) of ERISA, in relevant part, defines an automatic contribution arrangement as an arrangement under which "contributions are invested in accordance with regulations prescribed by the Secretary under section 404(c)(5)." Accordingly, the notice requirement in section 514(e)(3) of ERISA, as well as the related civil penalty provision in section 502(c)(4) of

ERISA, extend only to automatic contribution arrangements described in § 2550.404c-5(f)(1).

B. Overview of Section 2560.502c-4

In general, the final regulation sets forth how the maximum penalty amounts are computed, identifies the circumstances under which a penalty may be assessed, sets forth certain procedural rules for service and filing, and provides a plan administrator a means to contest an assessment by the Department and to request an administrative hearing.

Paragraph (a) of the regulation addresses the general application of section 502(c)(4) of ERISA, under which the plan administrator of an eligible plan shall be liable for civil penalties assessed by the Secretary of Labor in each case in which there is a failure or refusal, in whole or in part, to furnish the item(s) to each person entitled under the requirements of section 101(j), (k), or (l), or section 514(e)(3) of ERISA, as applicable.

Paragraph (b) of the regulation sets forth the amount of penalties that may be assessed under section 502(c)(4) of ERISA and provides that the penalty assessed under section 502(c)(4) for each separate violation is to be determined by the Department, taking into consideration the degree or willfulness of the failure or refusal. Paragraph (b) provides that the maximum amount assessed for each violation shall not exceed \$1,000 per day per violation.⁴

Paragraph (c) of the regulation provides that, prior to assessing a penalty under ERISA section 502(c)(4), the Department shall provide the plan administrator with written notice of the Department's intent to assess a penalty, the amount of such penalty, the number of individuals (*e.g.*, participants and beneficiaries) on which the penalty is based, the period to which the penalty applies, and the reason(s) for the penalty. The notice would indicate the specific provision violated (*i.e.*, section 101(j), (k), or (l), or section 514(e)(3) of ERISA). The notice is to be served in accordance with paragraph (i) of the regulation (service of notice provision).

⁴ The Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), Public Law 101-410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996 (the Act), Public Law 104-134, 110 Stat. 1321-373, generally provides that federal agencies adjust certain civil monetary penalties for inflation no later than 180 days after the enactment of the Act, and at least once every four years thereafter, in accordance with the guidelines specified in the 1990 Act. The Act specifies that any such increase in a civil monetary penalty shall apply only to violations that occur after the date the increase takes effect.

Paragraph (d) of the regulation provides that the Department may determine not to assess a penalty, or to waive all or part of the penalty to be assessed, under ERISA section 502(c)(4), upon a showing by the administrator, under paragraph (e) of the regulation, of compliance with section 101(j), (k), or (l), or section 514(e)(3) of ERISA or that there were mitigating circumstances for noncompliance. Under paragraph (e) of the regulation, the administrator has 30 days from the date of the service of the notice issued under paragraph (c) of the regulation within which to file a statement making such a showing. When the Department serves the notice under paragraph (c) by certified mail, service is complete upon mailing but five (5) days are added to the time allowed for the filing of the statement (see § 2560.502c-4(i)(2)).

Paragraph (f) of the regulation provides that a failure to file a timely statement under paragraph (e) shall be deemed to be a waiver of the right to appear and contest the facts alleged in the Department's notice of intent to assess a penalty for purposes of any adjudicatory proceeding involving the assessment of the penalty under section 502(c)(4) of ERISA, and to be an admission of the facts alleged in the notice of intent to assess. Such notice then becomes a final order of the Secretary 45 days from the date of service of the notice.

Paragraph (g)(1) of the regulation provides that, following a review of the facts alleged in the statement under paragraph (e), the Department shall notify the administrator of its intention to waive the penalty, in whole or in part, and/or assess a penalty. If it is the intention of the Department to assess a penalty, the notice shall indicate the amount of the penalty. Under paragraph (g)(2) of the regulation, this notice becomes a final order 45 days after the date of service of the notice, except as provided in paragraph (h).

Paragraph (h) of the regulation provides that the notice described in paragraph (g) will become a final order of the Department unless, within 30 days of the date of service of the notice, the plan administrator or representative files a request for a hearing to contest the assessment in administrative proceedings set forth in regulations issued under part 2570 of title 29 of the Code of Federal Regulations and files an answer, in writing, opposing the sanction. When the Department serves the notice under paragraph (g) by mail, service is complete upon mailing, but five days are added to the time allowed for the filing of a request for hearing and

³ Pursuant to section 101(c)(1)(A)(ii) of the Worker, Retiree, and Employer Recovery Act of 2008, Pub. L. 110-458, the Secretary of the Treasury, in consultation with the Secretary of Labor, shall have the authority to prescribe rules applicable to the notices required under section 101(j) of ERISA.

answer if the notice was served by certified mail (see 2560.502c-4(i)(2)).

Paragraph (i)(1) of the regulation describes the rules relating to service of the Department's notice of penalty assessment (Sec. 2560.502c-4(c)) and the Department's notice of determination on a statement of reasonable cause (Sec. 2560.502c-4(g)). Paragraph (i)(1) provides that service by the Department shall be made by delivering a copy to the administrator or representative thereof; by leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or by mailing a copy to the last known address of the administrator or representative thereof. As noted above, paragraph (i)(2) of this section provides that when service of a notice under paragraph (c) or (g) is by certified mail, service is complete upon mailing, but five days are added to the time allowed for the filing of a statement or a request for hearing and answer, as applicable. Service by regular mail is complete upon receipt by the addressee.

Paragraph (i)(3) of the regulation, which relates to the filing of statements of reasonable cause, provides that a statement of reasonable cause shall be considered filed (i) upon mailing if accomplished using United States Postal Service certified mail or express mail, (ii) upon receipt by the delivery service if accomplished using a "designated private delivery service" within the meaning of 26 U.S.C. 7502(f), (iii) upon transmittal if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment, or (iv) in the case of any other method of filing, upon receipt by the Department at the address provided in the notice. This provision does not apply to the filing of requests for hearing and answers with the Office of the Administrative Law Judge (OALJ) which are governed by the Department's OALJ rules in 29 CFR 18.4.

Paragraph (j) of the regulation clarifies the liability of the parties for penalties assessed under section 502(c)(4) of ERISA. Paragraph (j)(1) provides that, if more than one person is responsible as administrator for the failure to provide the required item(s), all such persons shall be jointly and severally liable for such failure. Paragraph (j)(2) provides that any person against whom a penalty is assessed under section 502(c)(4) of ERISA, pursuant to a final order, is personally liable for the payment of such penalty. Paragraph (j)(2) provides that liability for the payment of penalties assessed under section 502(c)(4) of ERISA is a personal liability of the person against whom the penalty

is assessed and not a liability of the plan. It is the Department's view that payment of penalties assessed under ERISA section 502(c) from plan assets would not constitute a reasonable expense of administering a plan for purposes of sections 403 and 404 of ERISA. Consistent with section 101(l) of ERISA, for purposes of any civil penalty imposed under section 502(c)(4) of ERISA pursuant to the requirements of section 101(l) of ERISA, the term "administrator" shall include plan sponsor (within the meaning of section 3(16)(B) of the Act).

Paragraph (k) of the regulation establishes procedures for hearings before an Administrative Law Judge (ALJ) with respect to assessment by the Department of a civil penalty under ERISA section 502(c)(4), and for appealing an ALJ decision to the Secretary or her delegate. The procedures are the same procedures that would apply in the case of a civil penalty assessment under section 502(c)(7) of ERISA.

C. Regulatory Impact Analysis

Executive Order 12866

Under Executive Order 12866 (58 FR 51735), the Department must determine whether a regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Pursuant to the terms of the Executive Order, it has been determined that this action is not "significant" within the meaning of section 3(f) of the Executive Order and therefore is not subject to review by OMB.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), imposes

certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. For purposes of its analyses under the RFA, EBSA continues to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reporting for pension plans that cover fewer than 100 participants.

The terms of the statute pertaining to the assessment of civil penalties under section 502(c)(4) of ERISA do not vary relative to plan or plan administrator size. The operation of the statute will normally result in the assessment of lower penalties where small plans are involved, because penalty assessments are based, in part, on the number of plan participants. The opportunity for a plan administrator to present facts and circumstances related to a failure or refusal to provide appropriate disclosure that may be taken into consideration by the Department in assessing penalties under ERISA section 502(c)(4) may offer some degree of flexibility to small entities subject to penalty assessments. Penalty assessments will have no direct impact on small plans, because the plan administrator assessed a civil penalty is personally liable for the payment of that penalty pursuant to section 2560.502c-4(j).

The Department invited interested persons to submit comments on the impact of this rule on small entities and on any alternative approaches that may serve to minimize the impact on small plans or other entities while accomplishing the objectives of the statutory provisions when the notice of proposed rulemaking was published; however, no comments on these issues were received.

Paperwork Reduction Act

The final regulation is not subject to the requirements of the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3501 *et seq.*), because it does not contain a collection of information as defined in 44 U.S.C. 3502(3). Information otherwise provided to the Secretary in connection with the administrative and procedural requirements of this final rule is excepted from coverage by PRA 95 pursuant to 44 U.S.C. 3518(c)(1)(B), and related regulations at 5 CFR 1320.4(a)(2) and (c). These provisions generally

except information provided as a result of an agency's civil or administrative action, investigation, or audit.

Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and the Comptroller General for review.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), as well as Executive Order 12875, this rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, and does not impose an annual burden exceeding \$100 million, as adjusted for inflation, on the private sector.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule does not have federalism implications because it has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in this final rule do not alter the fundamental reporting and disclosure, or administration and enforcement provisions of the statute with respect to employee benefit plans, and as such have no implications for the States or the relationship or distribution of power between the national government and the States.

List of Subjects in 29 CFR Part 2560

Employee benefit plans, Employee Retirement Income Security Act, Law enforcement, Pensions.

■ Accordingly, 29 CFR part 2560 is amended as follows:

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

■ 1. The authority citation for part 2560 continues to read as follows:

Authority: 29 U.S.C. 1132, 1135, and Secretary of Labor's Order 1-2003, 68 FR 5374 (Feb. 3, 2003). Sec. 2560.503-1 also issued under 29 U.S.C. 1133. Sections 2560.502c-7 and 2560.502c-4 also issued under Public Law 109-280, 120 Stat. 780.

■ 2. Add § 2560.502c-4 to read as follows:

§ 2560.502c-4 Civil penalties under section 502(c)(4).

(a) *In general.* (1) Pursuant to the authority granted the Secretary under section 502(c)(4) of the Employee Retirement Income Security Act of 1974, as amended (the Act), the administrator (within the meaning of section 3(16)(A) of the Act) shall be liable for civil penalties assessed by the Secretary under section 502(c)(4) of the Act, for failure or refusal to furnish:

- (i) Notice of funding-based limits in accordance with section 101(j) of the Act;
- (ii) Actuarial, financial or funding information in accordance with section 101(k) of the Act;
- (iii) Notice of potential withdrawal liability in accordance with section 101(l) of the Act; or
- (iv) Notice of rights and obligations under an automatic contribution arrangement in accordance with section 514(e)(3) of the Act.

(2) For purposes of this section, a failure or refusal to furnish the items referred to in paragraph (a)(1) above shall mean a failure or refusal to furnish, in whole or in part, the items required under section 101(j), (k), or (l), or section 514(e)(3) of the Act at the relevant times and manners prescribed in such sections.

(b) *Amount assessed.* (1) The amount assessed under section 502(c)(4) of the Act for each separate violation shall be determined by the Department of Labor, taking into consideration the degree or willfulness of the failure or refusal to furnish the items referred to in paragraph (a) of this section. However, the amount assessed for each violation under section 502(c)(4) of the Act shall not exceed \$1,000 a day (or such other maximum amount as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended), computed from the date of the administrator's failure or refusal to furnish the items referred to in paragraph (a) of this section.

(2) For purposes of calculating the amount to be assessed under this

section, a failure or refusal to furnish the item with respect to any person entitled to receive such item, shall be treated as a separate violation under section 101(j), (k), or (l), or section 514(e)(3) of the Act, as applicable.

(c) *Notice of intent to assess a penalty.* Prior to the assessment of any penalty under section 502(c)(4) of the Act, the Department shall provide to the administrator of the plan a written notice indicating the Department's intent to assess a penalty under section 502(c)(4) of the Act, the amount of such penalty, the number of individuals on which the penalty is based, the period to which the penalty applies, and the reason(s) for the penalty.

(d) *Reconsideration or waiver of penalty to be assessed.* The Department may determine that all or part of the penalty amount in the notice of intent to assess a penalty shall not be assessed on a showing that the administrator complied with the requirements of section 101(j), (k), or (l), or section 514(e)(3) of the Act, as applicable, or on a showing by such person of mitigating circumstances regarding the degree or willfulness of the noncompliance.

(e) *Showing of reasonable cause.* Upon issuance by the Department of a notice of intent to assess a penalty, the administrator shall have thirty (30) days from the date of service of the notice, as described in paragraph (i) of this section, to file a statement of reasonable cause explaining why the penalty, as calculated, should be reduced, or not be assessed, for the reasons set forth in paragraph (d) of this section. Such statement must be made in writing and set forth all the facts alleged as reasonable cause for the reduction or nonassessment of the penalty. The statement must contain a declaration by the administrator that the statement is made under the penalties of perjury.

(f) *Failure to file a statement of reasonable cause.* Failure to file a statement of reasonable cause within the thirty (30) day period described in paragraph (e) of this section shall be deemed to constitute a waiver of the right to appear and contest the facts alleged in the notice of intent, and such failure shall be deemed an admission of the facts alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(4) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.131(g) of this chapter, forty-five (45) days from the date of service of the notice.

(g) *Notice of determination on statement of reasonable cause.* (1) The Department, following a review of all of

the facts in a statement of reasonable cause alleged in support of nonassessment or a complete or partial waiver of the penalty, shall notify the administrator, in writing, of its determination on the statement of reasonable cause and its determination whether to waive the penalty in whole or in part, and/or assess a penalty. If it is the determination of the Department to assess a penalty, the notice shall indicate the amount of the penalty assessment, not to exceed the amount described in paragraph (c) of this section. This notice is a "pleading" for purposes of § 2570.131(m) of this chapter.

(2) Except as provided in paragraph (h) of this section, a notice issued pursuant to paragraph (g)(1) of this section, indicating the Department's determination to assess a penalty, shall become a final order, within the meaning of § 2570.131(g) of this chapter, forty-five (45) days from the date of service of the notice.

(h) *Administrative hearing.* A notice issued pursuant to paragraph (g) of this section will not become a final order, within the meaning of § 2570.131(g) of this chapter, if, within thirty (30) days from the date of the service of the notice, the administrator or a representative thereof files a request for a hearing under §§ 2570.130 through 2570.141 of this chapter, and files an answer to the notice. The request for hearing and answer must be filed in accordance with § 2570.132 of this chapter and § 18.4 of this title. The answer opposing the proposed sanction shall be in writing, and supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to paragraph (g) of this section.

(i) *Service of notices and filing of statements.* (1) Service of a notice for purposes of paragraphs (c) and (g) of this section shall be made:

(i) By delivering a copy to the administrator or representative thereof;

(ii) By leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or

(iii) By mailing a copy to the last known address of the administrator or representative thereof.

(2) If service is accomplished by certified mail, service is complete upon mailing. If service is by regular mail, service is complete upon receipt by the addressee. When service of a notice under paragraph (c) or (g) of this section is by certified mail, five days shall be added to the time allowed by these rules for the filing of a statement or a request for hearing and answer, as applicable.

(3) For purposes of this section, a statement of reasonable cause shall be considered filed:

(i) Upon mailing, if accomplished using United States Postal Service certified mail or express mail;

(ii) Upon receipt by the delivery service, if accomplished using a "designated private delivery service" within the meaning of 26 U.S.C. 7502(f);

(iii) Upon transmittal, if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment; or

(iv) In the case of any other method of filing, upon receipt by the Department at the address provided in the notice of intent to assess a penalty.

(j) *Liability.* (1) If more than one person is responsible as administrator for the failure to furnish the items required under section 101(j), (k), or (l), or section 514(e)(3) of the Act, as applicable, all such persons shall be jointly and severally liable for such failure. For purposes of paragraph (a)(1)(iii) of this section, the term "administrator" shall include plan sponsor (within the meaning of section 3(16)(B) of the Act).

(2) Any person, or persons under paragraph (j)(1) of this section, against whom a civil penalty has been assessed under section 502(c)(4) of the Act, pursuant to a final order within the meaning of § 2570.131(g) of this chapter shall be personally liable for the payment of such penalty.

(k) *Cross-references.* (1) The procedural rules in §§ 2570.130 through 2570.141 of this chapter apply to administrative hearings under section 502(c)(4) of the Act.

(2) When applying procedural rules in §§ 2570.130 through 2570.140:

(i) Wherever the term "502(c)(7)" appears, such term shall mean "502(c)(4)";

(ii) Reference to § 2560.502c-7(g) in 2570.131(c) shall be construed as reference to § 2560.502c-4(g) of this chapter;

(iii) Reference to § 2560.502c-7(e) in § 2570.131(g) shall be construed as reference to § 2560.502c-4(e) of this chapter;

(iv) Reference to § 2560.502c-7(g) in § 2570.131(m) shall be construed as reference to § 2560.502c-4(g); and

(v) Reference to §§ 2560.502c-7(g) and 2560.502c-7(h) in § 2570.134 shall be construed as reference to §§ 2560.502c-4(g) and 2560.502c-4(h), respectively.

Signed at Washington, DC, this 24th day of December 2008.

Bradford P. Campbell,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. E8-31188 Filed 12-31-08; 8:45 am]

BILLING CODE 4510-29-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2003-0118; FRL-8758-9]

RIN 2060-AG12

Protection of Stratospheric Ozone: Notice 23 for Significant New Alternatives Policy Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Determination of Acceptability.

SUMMARY: This Determination of Acceptability expands the list of acceptable substitutes for ozone-depleting substances under the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program. The determinations concern new substitutes for use in the refrigeration and air conditioning, fire suppression and explosion protection, and foam blowing sectors.

DATES: Effective January 2, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2003-0118 (continuation of Air Docket A-91-42). All electronic documents in the docket are listed in the index at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically at www.regulations.gov or in hard copy at the EPA Air Docket (No. A-91-42), 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 Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Margaret Sheppard by telephone at (202) 343-9163, by facsimile at (202) 343-2338, by e-mail at sheppard.margaret@epa.gov, or by mail at U.S. Environmental Protection

Agency, Mail Code 6205J, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Overnight or courier deliveries should be sent to the office location at 1310 L Street, NW., 10th floor, Washington, DC 20005.

For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the original SNAP rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044). Notices and rulemakings under the SNAP program, as well as other EPA publications on protection of stratospheric ozone, are available at EPA's Ozone Depletion World Wide Web site at <http://www.epa.gov/ozone/> including the SNAP portion at <http://www.epa.gov/ozone/snap/>.

SUPPLEMENTARY INFORMATION:

- I. Listing of New Acceptable Substitutes
 - A. Refrigeration and Air Conditioning
 - B. Fire Suppression and Explosion Protection
 - C. Foam Blowing
 - II. Section 612 Program
 - A. Statutory Requirements
 - B. Regulatory History
- Appendix A—Summary of Decisions for New Acceptable Substitutes

I. Listing of New Acceptable Substitutes

This section presents EPA's most recent acceptable listing decisions for substitutes in the refrigeration and air conditioning, fire suppression and explosion protection, and foam blowing sectors. For copies of the full list of ODS substitutes in all industrial sectors, visit EPA's Ozone Depletion Web site at <http://www.epa.gov/ozone/snap/lists/index.html>.

The sections below discuss each substitute listing in detail. Appendix A contains a table summarizing today's listing decisions for new substitutes. The statements in the "Further Information" column in the table provide additional information, but are not legally binding under section 612 of the Clean Air Act. In addition, the "further information" may not be a comprehensive list of other legal obligations you may need to meet when using the substitute. Although you are not required to follow recommendations in the "further information" column of the table to use a substitute, EPA strongly encourages you to apply the information when using these substitutes. In many instances, the information simply refers to standard operating practices in existing industry and/or building-code standards. Thus, many of these statements, if adopted, would not require significant changes to existing operating practices.

You can find submissions to EPA for the use of the substitutes listed in this document and other materials supporting the decisions in this action in docket EPA-HQ-OAR-2003-0118 at <http://www.regulations.gov>.

A. Refrigeration and Air Conditioning

1. R-407A

EPA's decision:

R-407A [R-32/125/134a (20.0/40.0/40.0)] is acceptable for use in new and retrofit equipment as a substitute for hydrochlorofluorocarbon (HCFC)-22 and HCFC blends including, but not limited to, R-401A, R-401B, R-402A, and R-402B in:

- Retail food refrigeration.
- Cold storage warehouses.
- Refrigerated transport.
- Residential and light commercial air conditioning and heat pumps.

R-407A is a blend of 40.0% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 40.0% by weight HFC-134a (1,1,1,2-tetrafluoroethane, CAS ID #811-97-2), and 20.0% by weight HFC-32 (difluoromethane, CAS ID #75-10-5). This blend is also known by the trade names KLEA 60, KLEA 407A, and others. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0167 at

www.regulations.gov.

Environmental information:

The ozone depletion potential (ODP) of R-407A is zero. The global warming potentials (GWPs) of HFC-125, HFC-134a, and HFC-32 are 3500, 1430, and 675, respectively (relative to carbon dioxide), using a 100-year time horizon (The International Panel on Climate Change [IPCC], Fourth Assessment Report, *Climate Change 2007: The Physical Science Basis*). The atmospheric lifetimes of these constituents are 29, 14, and 4.9 years, respectively.

The contribution of this blend to greenhouse gas emissions will be reduced given the venting prohibition under section 608(c)(2) of the Clean Air Act. This section and EPA's implementing regulations codified at 40 CFR part 82, subpart F prohibit the intentional venting or release of substitutes for class I or class II ODSs used during the repair, maintenance, service or disposal of refrigeration and air conditioning equipment (i.e., appliances).

HFC-125, HFC-134a, and HFC-32 are excluded from the definition of volatile organic compound (VOC) under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of State Implementation Plans (SIPs) to attain and maintain the national ambient air quality standards.

Flammability information:

While one of the blend components, HFC-32, is flammable, the blend as formulated and under worst case fractionated formulation scenarios is not flammable.

Toxicity and exposure data:

Potential health effects of this substitute at lower concentrations include dizziness and loss of concentration. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, it may cause central nervous system depression, irregular heart beat, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

To protect against these potential health risks, HFC-125, HFC-134a, and HFC-32 have 8 hour/day, 40 hour/week workplace environmental exposure limits (WEELs) of 1000 ppm established by the American Industrial Hygiene Association (AIHA). EPA recommends that users follow all requirements and recommendations specified in the Material Safety Data Sheet (MSDS) for the blend and the individual components and other safety precautions common in the refrigeration and air conditioning industry. We also recommend that users of R-407A adhere to the AIHA's WEELs. EPA anticipates that users will be able to meet the WEELs and will be able to address potential health risks by following requirements and recommendations in the MSDSs and other safety precautions common in the refrigeration and air conditioning industry.

Comparison to other refrigerants:

R-407A is not an ozone depleter in contrast to the ozone-depleting substances which it replaces. R-407A is comparable to other substitutes for HCFC-22 and its blends in its lack of risk for ozone depletion. (HCFC-22 has an ODP of 0.05 and a GWP of 1810, according to the *Scientific Assessment of Ozone Depletion: 2006* prepared by the World Meteorological Organization (WMO, 2006).) R-407A has a GWP of about 2100, comparable to or lower than that of other substitutes for HCFC-22. For example, the GWP of R-407C is about 3350, the GWP of R-410A is about 2100, and the GWP of R-507 is about 4000. Flammability and toxicity risks are low, as discussed above. Thus, we find that R-407A is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

2. KDD6

EPA's decision:

KDD6 is acceptable for use in new and retrofit equipment as a substitute for CFC-12 in:

- Chillers (screw, reciprocating).
- Industrial process refrigeration.
- Industrial process air conditioning.
- Retail food refrigeration.
- Cold storage warehouses.
- Refrigerated transport.
- Commercial ice machines.
- Ice skating rinks.
- Household refrigerators and freezers.
- Vending machines.
- Water coolers.
- Residential dehumidifiers.
- Residential and light commercial air conditioning and heat pumps.
- Non-mechanical heat transfer.

The submitter of KDD6 has claimed its composition as confidential business information. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0197 at www.regulations.gov.

Environmental information:

The ODP of KDD6 is zero. The average 100-year integrated GWP of this blend is between 2100 and 3350, in the range of the GWPs for R-407C and R-410A, two other commonly used substitute refrigerants.

The contribution of this blend to greenhouse gas emissions will be reduced given the venting prohibition under section 608(c)(2) of the Clean Air Act. This section and EPA's implementing regulations codified at 40 CFR part 82, subpart F prohibit the intentional venting or release of substitutes for class I or class II ODSs used during the repair, maintenance, service or disposal of refrigeration and air conditioning equipment (i.e., appliances).

Some components of the blend are VOCs under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards.

Flammability information:

While at least one of the blend components is flammable, the blend as formulated and under worst-case fractionated formulation scenarios is not flammable.

Toxicity and exposure data:

Potential health effects of this substitute at lower concentrations include dizziness and loss of concentration. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, it may cause central nervous system depression, irregular

heart beat, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

To protect against these potential health risks, the manufacturer recommends an 8-hr TWA workplace exposure limit for the blend of 994 ppm. A number of components of the blend have workplace exposure limits of 1000 ppm set by the manufacturer, the AIHA, or the ACGIH. EPA anticipates that users will be able to meet the manufacturer's recommended workplace exposure limit and will be able to address potential health risks by following requirements and recommendations in the MSDS and other safety precautions common in the refrigeration and air conditioning industry.

Comparison to other refrigerants:

KDD6 is not an ozone depleter; thus, it poses a lower risk for ozone depletion than the ODS it replaces. KDD6 has comparable or lower risk for ozone depletion than other substitutes for CFC-12. (CFC-12 has an ODP of 1.0 and a GWP of 10,890 (WMO, 2006).) KDD6 has a GWP comparable to or lower than that of other substitutes for CFC-12. For example, the GWP of R-407C is about 3350, the GWP of R-410A is about 2100, and the GWP of R-507 is about 4000. Flammability and toxicity risks are low, as discussed above. We find that KDD6 is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

3. R-427A

EPA's decisions:

R-427A [R-32/125/143a/134a (15.0/25.0/10.0/50.0)] is acceptable for use in retrofit equipment as a substitute for HCFC-22 in:

- Retail food refrigeration.
- Industrial process air conditioning.
- Reciprocating chillers.
- Screw chillers.
- Household refrigerators and freezers.
- Residential and light commercial air conditioning and heat pumps.
- Motor vehicle air conditioning (buses and passenger trains only).

R-427A is a blend of 25.0% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 50% by weight HFC-134a (1,1,1,2-tetrafluoroethane, CAS ID #811-97-2), 10.0% by weight HFC-143a (1,1,1-trifluoroethane, CAS ID #420-46-2), and 15.0% HFC-32 (difluoromethane, CAS ID #75-10-5). A common trade name for this refrigerant is Forane 427A. You may find the

submission under Docket item EPA-HQ-OAR-2003-0118-0177 at www.regulations.gov.

Environmental information:

The ODP of R-427A is zero. The GWPs of HFC-125, HFC-134a, HFC-143a, and HFC-32 are 3500, 1430, 4470, and 675, respectively. The atmospheric lifetimes of these constituents are 29, 14, 52, and 4.9 years, respectively.

The contribution of this blend to greenhouse gas emissions will be reduced given the venting prohibition under section 608(c)(2) of the Clean Air Act. This section and EPA's implementing regulations codified at 40 CFR part 82, subpart F prohibit the intentional venting or release of substitutes for class I or class II ODSs used during the repair, maintenance, service or disposal of refrigeration and air conditioning equipment (i.e., appliances).

HFC-32, HFC-125, HFC-134a, and HFC-143a are exempt from the definition of VOC under Clean Air Act regulations concerning the development of SIPs to attain and maintain the national ambient air quality standards. 40 CFR 51.100(s).

Flammability information:

While two components of the blend, HFC-32 and HFC-143a, are flammable, the blend as formulated and under worst-case fractionated formulation scenarios is not flammable.

Toxicity and exposure data:

Potential health effects of this substitute at lower concentrations include dizziness and loss of concentration. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, it may cause central nervous system depression, irregular heart beat, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

To protect against these potential health risks, HFC-125, HFC-134a, HFC-143a and HFC-32 have 8 hour/day, 40 hour/week WEELS of 1000 ppm established by the AIHA. EPA recommends that users follow all requirements and recommendations specified in the MSDS for the blend and the individual components and other safety precautions common in the refrigeration and air conditioning industry. EPA also recommends that users of R-427A adhere to the AIHA's WEELS. EPA anticipates that users will be able to meet the WEELS and will be able to address potential health risks by following requirements and recommendations in the MSDSs and other safety precautions common in the

refrigeration and air conditioning industry.

Comparison to other refrigerants:

R-427A is not an ozone depleter in contrast to HCFC-22, the ozone depleting substance which it replaces. R-427A is comparable to other substitutes for HCFC-22 in its lack of risk for ozone depletion. (HCFC-22 has an ODP of 0.05 and a GWP of 1810 (WMO, 2006).) R-427A has a GWP of about 2150, comparable to or lower than that of other substitutes for HCFC-22. For example, the GWP of R-407C is about 3350, the GWP of R-410A is about 2100, and the GWP of R-507 is about 4000. The flammability and toxicity risks are low, as discussed above. Thus, we find that R-427A is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

4. R-424A (RS-44)

EPA's decision:

R-424A [R-125/134a/600a/600/601a (50.5/47.0/0.9/1.0/0.6)] is acceptable for use in new and retrofit equipment as a substitute for HCFC-22 in motor vehicle air conditioning (buses and passenger trains only).

R-424A is a blend of 50.5% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 47.0% by weight HFC-134a (1,1,1,2-tetrafluoroethane, CAS ID #811-97-2), 0.9% by weight R-600a (isobutane, 2-methyl propane, CAS ID #75-28-5), 1.0% by weight R-600 (n-butane, CAS ID #106-97-8), and 0.6% by weight R-601a (isopentane, 2-methylbutane, CAS ID #78-78-4). A common trade name for this refrigerant is RS-44. This formulation for RS-44 is different from the first formulation that EPA found acceptable in several refrigerant end uses (August 21, 2003; 68 FR 50533). EPA previously found the current formulation of RS-44, also designated as R-424A, acceptable as a substitute for R-22 in a number of other refrigeration and air conditioning end uses (September 28, 2006, 71 FR 56884). You may find additional information under Docket item EPA-HQ-OAR-2003-0118-0131 at www.regulations.gov.

Environmental information:

The ODP of R-424A is zero. The GWPs of HFC-125 and HFC-134a are 3500 and 1430 and their atmospheric lifetimes are 29 and 14 years, respectively. The GWPs of isobutane, n-butane, and isopentane are not provided in the IPCC's Fourth Assessment Report, but are generally believed to be low (less than 10), and their atmospheric lifetimes are less than one year (see Table 2.8 in *Safeguarding the Ozone*

Layer and the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons, prepared by the IPCC and the Technology and Economic Assessment Panel of the Montreal Protocol).

The contribution of this blend to greenhouse gas emissions will be reduced given the venting prohibition under section 608(c)(2) of the Clean Air Act. This section and EPA's implementing regulations codified at 40 CFR part 82, subpart F prohibit the intentional venting or release of substitutes for class I or class II ODSs used during the repair, maintenance, service or disposal of refrigeration and air conditioning equipment (i.e., appliances).

Isobutane, n-butane, and isopentane are VOCs under Clean Air Act regulations (see 40 CFR 51.100(s)) concerning the development of SIPs to attain and maintain the national ambient air quality standards. HFC-125 and HFC-134a are excluded from the definition of VOC under these regulations.

Flammability information:

While three components of the blend are flammable, the blend as formulated, and under worst-case fractionated formulation scenarios, is not flammable.

Toxicity and exposure data:

Potential health effects of this substitute at lower concentrations include dizziness and loss of concentration. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, it may cause central nervous system depression, irregular heart beat, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

To protect against these potential health risks, HFC-125 and HFC-134a have 8 hour/day, 40 hour/week WEELs of 1000 ppm established by the AIHA. Isobutane, n-butane and isopentane, have 8 hour/day, 40 hour/week threshold limit values (TLVs) established by the American Conference of Governmental Industrial Hygienists (ACGIH) of 1000 ppm, 800 ppm and 600 ppm, respectively. EPA recommends that users follow all requirements and recommendations specified in the MSDS for the blend and the individual components and other safety precautions common in the refrigeration and air conditioning industry. EPA also recommends that users of R-424A adhere to the AIHA's WEELs and the ACGIH's TLVs. EPA anticipates that users will be able to meet the WEELs and TLVs and will be able to address

potential health risks by following requirements and recommendations in the MSDSs and other safety precautions common in the refrigeration and air conditioning industry.

Comparison to other refrigerants:

R-424A is not an ozone depleter in contrast to HCFC-22 which it replaces. It is comparable to other substitutes for HCFC-22 in its lack of risk for ozone depletion. (HCFC-22 has an ODP of 0.05 and a GWP of 1810 (WMO, 2006).) R-424A has a GWP of about 2400, lower than that of some substitutes for HCFC-22 but higher than others. For example, the GWP of R-407C is about 3350, the GWP of R-410A is about 2100, and the GWP of R-507 is about 4000. Flammability and toxicity risks are low, as discussed above. Thus, we find that R-424A is acceptable because it does not pose a greater overall risk to public health and the environment in the end use listed above.

5. R-434A (RS-45)

EPA's decision:

R-434A [R-125/143a/134a/600a (63.2/18.0/16.0/2.8)] is acceptable for use in new and retrofit equipment as a substitute for HCFC-22 in motor vehicle air conditioning (buses and passenger trains only).

R-434A is a blend of 18.0% by weight HFC-143a (1,1,1-trifluoroethane, CAS ID #420-46-2), 63.2% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 16.0% by weight HFC-134a (1,1,1,2-tetrafluoroethane, CAS ID #811-97-2), and 2.8% by weight R-600a (isobutane, 2-methyl propane, CAS ID #75-28-5). A common trade name for this refrigerant is RS-45. Under that trade name, EPA previously found R-434A acceptable as a substitute for R-22 in a number of other refrigeration and air conditioning end uses (October 4, 2007, 72 FR 56628). You may find additional information under Docket item EPA-HQ-OAR-2003-0118-0162 at www.regulations.gov.

Environmental information:

The ODP of R-434A is zero. The GWPs of HFC-143a, HFC-125, HFC-134a, and isobutane are 4470, 3500, 1430, and less than 10, respectively. The atmospheric lifetimes of these constituents are 52, 29, and 14 years, and less than one year, respectively.

The contribution of this blend to greenhouse gas emissions will be reduced given the venting prohibition under section 608(c)(2) of the Clean Air Act. This section and EPA's implementing regulations codified at 40 CFR part 82, subpart F prohibit the intentional venting or release of substitutes for class I or class II ODSs used during the repair, maintenance,

service or disposal of refrigeration and air conditioning equipment (i.e., appliances).

HFC-143a, HFC-125 and HFC-134a are excluded from the definition of VOC under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards. Isobutane is a VOC under Clean Air Act regulations.

Flammability information:

While two of the blend components, isobutane and HFC-143a, are flammable, the blend as formulated and under worst case fractionated formulation scenarios is not flammable.

Toxicity and exposure data:

Potential health effects of this substitute at lower concentrations include dizziness and loss of concentration. The substitute may also irritate the skin or eyes or cause frostbite. At sufficiently high concentrations, it may cause central nervous system depression, irregular heart beat, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

To protect against these potential health risks, HFC-143a has an 8 hour/day, 40 hour/week recommended acceptable exposure limit for the workplace from the manufacturer of 1000 ppm. HFC-125 and HFC-134a have 8 hour/day, 40 hour/week WEELS of 1000 ppm established by the AIHA. Isobutane has an 8 hour/day, 40 hour/week TLV established by the ACGIH of 1000 ppm. EPA recommends that users follow all requirements and recommendations specified in the Material Safety Data Sheet (MSDS) for the blend and the individual components and other safety precautions common in the refrigeration and air conditioning industry. EPA also recommends that users of R-434A adhere to the AIHA's WEELS and the ACGIH's TLV. EPA anticipates that users will be able to meet the WEELS and the TLV and will be able to address potential health risks by following requirements and recommendations in the MSDS and other safety precautions common in the refrigeration and air conditioning industry.

Comparison to other refrigerants:

R-434A is not an ozone depleter in contrast to HCFC-22, the ozone-depleting substance which it replaces. R-434A is comparable to other substitutes for HCFC-22 in its lack of risk for ozone depletion. (HCFC-22 has an ODP of 0.05 and a GWP of 1810 (WMO, 2006).) R-434A has a GWP of about 3200, lower than that of some

substitutes for HCFC-22, but higher than others. For example, the GWP of R-407C is about 3350, the GWP of R-410A is about 2100, and the GWP of R-507 is about 4000. Flammability and toxicity risks are low, as discussed above. Thus, we find that R-434A is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end use listed above.

B. Fire Suppression and Explosion Protection

1. Victaulic Vortex System

EPA's decision:

The Victaulic Vortex System is acceptable as a halon 1301 substitute for total flooding uses in both occupied and unoccupied areas.

The Victaulic Vortex System is a fire suppression system that uses fine water vapor droplets and nitrogen gas (N₂, CAS ID #7727-37-9). It is designed for use with Class A and Class B fires. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0172 at www.regulations.gov.

Environmental information:

The ozone depletion potential (ODP) and the global warming potential (GWP) of each of the constituents of the Victaulic Vortex System is zero.

The Victaulic Vortex System does not contain volatile organic compounds (VOC) as defined under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards.

Flammability information:

The Victaulic Vortex System is non-flammable.

Toxicity and exposure data:

The potential health risks of the Victaulic Vortex System come from N₂, an inert gas that at sufficiently high levels can cause asphyxiation. The Victaulic Vortex System can be designed to ensure that the oxygen concentration in any protected space will not fall below 12 percent over the 5 minute discharge period, consistent with the health criteria in National Fire Protection Agency (NFPA) Standard 2001 for Clean Agent Fire Extinguishing Systems. EPA recommends that use of this system should be in accordance with the safe exposure guidelines for inert gas systems in the latest edition of NFPA 2001, specifically the requirements for residual oxygen levels, and that use should be in accordance with the relevant operational requirements in NFPA 750 Standard on Water Mist Fire Protection Systems.

EPA also recommends that Section VIII of the Occupational Safety & Health Administration (OSHA) Technical Manual be consulted for information on selecting the appropriate types of Personal Protective Equipment (PPE) recommended.

Comparison to other fire suppressants:

The Victaulic Vortex System is not an ozone depleter in contrast to the ozone depleting substance which it replaces. The Victaulic Vortex System has comparable or lower risk for ozone depletion than other substitutes for halon 1301. (Halon 1301 has an ODP of 16 and a GWP of 7140 (WMO, 2006).) The Victaulic Vortex System has a GWP of zero, comparable to or lower than that of other substitutes for halon 1301. For example, the GWP of HFC-227ea is 3220, the GWP of HFC-125 is 3500, and the GWP of HFC-236fa is 9810. The flammability and toxicity risks are low and are comparable or lower than for other acceptable fire suppressants such as IG-100 (N₂), as discussed above. Thus, we find that the Victaulic Vortex System is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end use listed above.

2. ATK OS-10

EPA's decision:

The ATK OS-10 system is acceptable as a halon 1301 substitute for total flooding uses in both occupied and unoccupied areas.

The OS-10 system is a fire suppression system that uses gas generators, either singly or several grouped together in a casing, to suppress fires through production mainly of water vapor and nitrogen (N₂, CAS ID #7727-37-9). You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0198 at www.regulations.gov.

Environmental information:

The ODP of each of the gaseous post-activation products of the OS-10 system is zero. The GWPs of the gaseous post-activation products of OS-10 are 1 or less.

The OS-10 system does not contain VOCs as defined under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards.

Flammability information:

The OS-10 system is non-flammable.

Toxicity and exposure data:

Upon activation, OS-10 system produces post-activation products mainly consisting of gases and some

particulates. The main post-activation gaseous products are water and N₂, an inert gas that at sufficiently high levels can cause asphyxiation. The OS-10 system can be designed to ensure that the oxygen concentration in any protected space will not fall below 12 percent over the 5 minute discharge period, consistent with the health criteria in National Fire Protection Agency (NFPA) Standard 2001 for Clean Agent Fire Extinguishing Systems. Testing data provided by the submitter indicate that there will not be a significant amount of particulate left in the room after discharge. Thus, EPA believes that potential toxicity and nuisance dust effects from exposure to the particulate matter should not be detrimental to human health within the five-minute egress timeframe established for total flooding fire extinguishing systems by the NFPA Standard 2001 (NFPA 2008). EPA recommends that use of this system should be in accordance with the safe exposure guidelines for inert gas systems in the latest edition of NFPA 2001, specifically the requirements for residual oxygen levels, and that use should be in accordance with the relevant operational requirements in NFPA Standard 2010 for Aerosol Extinguishing Systems.

Installation and maintenance personnel should receive training in order to minimize the risk for accidental discharge of the system while performing installation or maintenance activities. Exposure of personnel during cleanup should be minimized by increasing the air exchange rate in the room prior to cleanup in order to aerate the space and reduce humidity. In addition, EPA recommends that all workers entering the protected volume to clean up after activation should wear appropriate personal protective equipment (PPE). We recommend consulting section VIII of the Occupational Safety & Health Administration (OSHA) Technical Manual (OSHA 1999) as well as all information from the manufacturer for information on selecting appropriate types of PPE to be worn by personnel involved in the manufacture, installation, maintenance, or clean up of OS-10.

Comparison to other fire suppressants:

The OS-10 system is not an ozone depleter in contrast to the ozone depleting substance which it replaces. OS-10 has comparable or lower risk for ozone depletion than other substitutes for halon 1301. (Halon 1301 has an ODP of 16 and a GWP of 7140 (WMO, 2006).) The gaseous post-activation products of

OS-10 have GWPs well below those of other substitutes for halon 1301. For example, the GWPs of all of the OS-10 gases are less than 1 compared to the GWP of HFC-227ea at 3220, the GWP of HFC-125 at 3500, and the GWP of HFC-236fa at 9810. The flammability and toxicity risks are low and are comparable or lower than for other acceptable fire suppressants such as IG-100 (N₂), as discussed above. Thus, we find that the OS-10 system is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end use listed above.

C. Foam Blowing

1. Formacel® B

EPA's decision:

Formacel® B is acceptable as a substitute for HCFC-22 and HCFC-142b in polystyrene, extruded boardstock and billet.

Formacel® B is a series of blends of the same component compounds. The submitter has claimed its composition as confidential business information. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0179 at www.regulations.gov.

Environmental information:

Formacel® B has no ODP. Formacel® B blends range in global warming potential (GWP) from approximately 140 to 1500. Formacel® B does not contain volatile organic compounds (VOC) as defined under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards.

Flammability information:

Some components of the Formacel® B blends are flammable. Some specific blends are flammable as formulated and should be handled with proper precautions. EPA recommends that users follow all requirements and recommendations specified in the Material Safety Data Sheet (MSDS) and other safety precautions for use of flammable blowing agents used in the foam blowing industry. Use of Formacel® B will require safe handling and shipping as prescribed by the Occupational Safety and Health Administration (OSHA) and the Department of Transportation (for example, using personal safety equipment and following requirements for shipping hazardous materials at 49 CFR parts 170 through 173).

Toxicity and exposure data:

Potential health effects of this substitute include nausea, headache, weakness, or central nervous system

depression with effects such as dizziness, headache, or confusion. The substitute may also irritate the lungs, skin or eyes or cause frostbite. At high concentrations, the substitute may also cause irregular heart beat, abnormal kidney function, loss of consciousness, or death. The substitute could cause asphyxiation, if air is displaced by vapors in a confined space. These potential health effects are common to many foam blowing agents.

EPA anticipates that Formacel® B will be used consistent with the recommendations specified in the manufacturers' Material Safety Data Sheets (MSDSs). The manufacturer recommends a workplace exposure limit of 1000 ppm for Formacel® B. EPA anticipates that users will be able to meet the manufacturer's recommended workplace exposure limits and will be able to address potential health risks by following requirements and recommendations in the MSDSs and other safety precautions common in the foam blowing industry.

Comparison to other foam blowing agents:

Formacel® B is not ozone depleting in contrast to the ozone depleting substances which it replaces. Formacel® B has comparable or lower risk for ozone depletion than other substitutes for HCFC-22 and HCFC-142b. (HCFC-22 and HCFC-142b have ODPs of 0.05 and 0.07 and GWPs of 1810 and 2310, respectively (WMO, 2006).) Formacel® B blends range in GWP from 140 to 1500, comparable to or lower than that of other substitutes for HCFC-22 and HCFC-142b. For example, the GWP of HFC-134a is about 1430 and the GWP of HFC-245fa is about 1030. Flammability risks can be addressed by procedures common in the industry. The toxicity risks are low, as discussed above. Thus, we find that Formacel® B is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end use listed above.

II. Section 612 Program

A. Statutory Requirements

Section 612 of the Clean Air Act authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances. We refer to this program as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

- *Rulemaking*—Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, and

hydrobromofluorocarbon) or class II (hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

- *Listing of Unacceptable/Acceptable Substitutes*—Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. We must publish a corresponding list of acceptable alternatives for specific uses.

- *Petition Process*—Section 612(d) grants the right to any person to petition EPA to add a substance to or delete a substance from the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, it must publish the revised lists within an additional six months.

- *90-day Notification*—Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

- *Outreach*—Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

- *Clearinghouse*—Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. Regulatory History

On March 18, 1994, EPA published the final rulemaking (59 FR 13044) that described the process for administering the SNAP program and issued our first acceptability lists for substitutes in the major industrial use sectors. These sectors include:

- Refrigeration and air conditioning;
- Foam blowing;
- Solvents cleaning;
- Fire suppression and explosion protection;
- Sterilants;
- Aerosols;
- Adhesives, coatings and inks; and
- Tobacco expansion.

These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ozone-depleting compounds.

As described in this original rule for the SNAP program, EPA does not believe that rulemaking procedures are required to list alternatives as acceptable with no limitations. Such listings do not impose any sanction, nor do they remove any prior license to use a substance. Therefore, by this notice we are adding substances to the list of acceptable alternatives without first requesting comment on new listings.

However, we do believe that notice-and-comment rulemaking is required to place any substance on the list of prohibited substitutes, to list a substance as acceptable only under certain conditions, to list substances as

acceptable only for certain uses, or to remove a substance from the lists of prohibited or acceptable substitutes. We publish updates to these lists as separate notices of rulemaking in the **Federal Register**.

The Agency defines a “substitute” as any chemical, product substitute, or alternative manufacturing process, whether existing or new, intended for use as a replacement for a class I or class II substance. Anyone who plans to market or produces a substitute for an ODS in one of the eight major industrial use sectors must provide EPA with health and safety studies on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. This requirement applies to substitute manufacturers, but may include importers, formulators, or end-users, when they are responsible for introducing a substitute into commerce.

You can find a complete chronology of SNAP decisions and the appropriate **Federal Register** citations from the SNAP section of EPA's Ozone Depletion World Wide Web site at <http://www.epa.gov/ozone/snap/chron.html>. This information is also available from the Air Docket (see **ADDRESSES** section above for contact information).

List of Subjects in 40 CFR Part 82

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

Dated: December 22, 2008.

Dina Kruger,

Acting Director, Office of Atmospheric Programs.

Appendix A: Summary of Acceptable Decisions

End-use	Substitute	Decision	Further information
Refrigeration and Air Conditioning			
Screw chillers (retrofit)	R-427A as a substitute for HCFC-22.	Acceptable.	
Screw chillers (retrofit and new)	KDD6 as a substitute for CFC-12	Acceptable.	
Reciprocating chillers (retrofit)	R-427A as a substitute for HCFC-22.	Acceptable.	
Reciprocating chillers (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Industrial process refrigeration (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Industrial process air conditioning (retrofit).	R-427A as a substitute for HCFC-22.	Acceptable.	
Industrial process air conditioning (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Retail food refrigeration (retrofit)	R-427A as a substitute for HCFC-22.	Acceptable.	
Retail food refrigeration (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	

End-use	Substitute	Decision	Further information
Cold storage warehouses (retrofit and new).	R-407A as a substitute for HCFC-22 and HCFC blends including R-401A, R-401B, R-402A, and R-402B. KDD6 as a substitute for CFC-12	Acceptable. Acceptable.	
Refrigerated transport (retrofit and new).	R-407A as a substitute for HCFC-22 and HCFC blends including R-401A, R-401B, R-402A, and R-402B. KDD6 as a substitute for CFC-12	Acceptable. Acceptable.	
Commercial ice machines (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Ice skating rinks (retrofit and new)	KDD6 as a substitute for CFC-12	Acceptable.	
Household refrigerators and freezers (retrofit).	R-427A as a substitute for HCFC-22.	Acceptable.	
Household refrigerators and freezers (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Vending machines (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Water coolers (retrofit and new)	KDD6 as a substitute for CFC-12	Acceptable.	
Residential dehumidifiers (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	
Residential and light commercial air conditioning and heat pumps (retrofit).	R-427A as a substitute for HCFC-22.	Acceptable.	
Residential and light commercial air conditioning and heat pumps (retrofit and new).	R-407A as a substitute for HCFC-22 and HCFC blends including R-401A, R-401B, R-402A, and R-402B. KDD6 as a substitute for CFC-12	Acceptable. Acceptable.	
Motor vehicle air conditioning for buses and passenger trains only (retrofit).	R-427A as a substitute for HCFC-22.	Acceptable.	
Motor vehicle air conditioning for buses and passenger trains only (retrofit and new).	R-424A (RS-44, new formulation) as a substitute for HCFC-22. R-434A (RS-45) as a substitute for HCFC-22.	Acceptable. Acceptable.	
Non-mechanical heat transfer (retrofit and new).	KDD6 as a substitute for CFC-12	Acceptable.	

Foam Blowing

Polystyrene, Extruded Boardstock & Billet.	Formace® B as a substitute for HCFC-22 and HCFC-142b.	Acceptable	Observe recommendations in the manufacturer's MSDS and guidance for using these blends.
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Fire Suppression and Explosion Protection

Total flooding	Victaulic Vortex System as a substitute for halon 1301.	Acceptable	<p>EPA recommends that users consult Section VIII of the Occupational Safety & Health Administration (OSHA) Technical Manual for information on selecting the appropriate types of Personal Protective Equipment (PPE).</p> <p>EPA recommends that use of this system should be in accordance with the safe exposure guidelines for inert gas systems in the latest edition of NFPA 2001, specifically the requirements for residual oxygen levels, and should be in accordance with the relevant operational requirements in NFPA 750 Standard on Water Mist Fire Protection Systems.</p> <p>Use should conform with relevant OSHA requirements, including 29 CFR part 1910, subpart L, sections 1910.160 and 1910.162.</p>
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End-use	Substitute	Decision	Further information
Total flooding	ATK OS-10 as a substitute for halon 1301.	Acceptable	<p>EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protection equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.</p> <p>EPA recommends that users consult Section VIII of the Occupational Safety & Health Administration (OSHA) Technical Manual for information on selecting the appropriate types of Personal Protective Equipment (PPE).</p> <p>EPA recommends that use of this system should be in accordance with the safe exposure guidelines for inert gas systems in the latest edition of NFPA 2001, specifically the requirements for residual oxygen levels, and should be in accordance with the relevant operational requirements in NFPA Standard 2010 for Aerosol Extinguishing Systems.</p> <p>Use should conform with relevant OSHA requirements, including 29 CFR part 1910, subpart L, sections 1910.160 and 1910.162.</p> <p>EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protection equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.</p>

[FR Doc. E8-31225 Filed 12-31-08; 8:45 am]
 BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE

50 CFR Part 648

[Docket No. 0809251266-81485-02]

RIN 0648-XJ96

Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; 2009 Summer Flounder, Scup, and Black Sea Bass Specifications; Preliminary 2009 Quota Adjustments; 2009 Summer Flounder Quota for Delaware

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

ACTION: Final rule.

SUMMARY: NMFS issues final specifications for the 2009 summer flounder, scup, and black sea bass fisheries. This final rule specifies allowed harvest limits for both commercial and recreational fisheries, including commercial scup possession limits. This action prohibits federally permitted commercial vessels from landing summer flounder in Delaware in 2009 due to continued quota repayment from previous years' overages.

The actions of this final rule are necessary to comply with regulations implementing the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP), as well as to ensure compliance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

The intent of this action is to establish harvest levels and other management measures to ensure that target fishing mortality rates (F) or exploitation rates, as specified for these species in the FMP, are not exceeded. In addition, this action implements measures that ensure continued rebuilding of these three stocks that are currently under rebuilding plans.

DATES: Effective January 1, 2009, through December 31, 2009.

ADDRESSES: Copies of the specifications document, including the Environmental Assessment (EA), Regulatory Impact Review (RIR), Initial Regulatory Flexibility Analysis (IRFA), and other supporting documents used by the Summer Flounder, Scup, and Black Sea Bass Monitoring Committees and Scientific and Statistical Committee are available from Daniel Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19901-6790. The specifications document is also accessible via the Internet at <http://www.nero.noaa.gov>.

The Final Regulatory Flexibility Analysis (FRFA) consists of the IRFA, public comments and responses contained in this final rule, and the summary of impacts and alternatives contained in this final rule. Copies of the small entity compliance guide are available from Patricia A. Kurkul, Regional Administrator, Northeast Region, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930-2298.

FOR FURTHER INFORMATION CONTACT: Michael Ruccio, Fishery Policy Analyst, (978) 281-9104.

SUPPLEMENTARY INFORMATION:

Background

The summer flounder, scup, and black sea bass fisheries are managed cooperatively under the provisions of the FMP developed by the Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission (Commission), in consultation with the New England and South Atlantic Fishery Management Councils. The management units specified in the FMP include summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina (NC) northward to the U.S./Canada border, and scup (*Stenotomus chrysops*) and black sea bass (*Centropristis striata*) in U.S. waters of the Atlantic Ocean from 35°13.3' N. lat. (the latitude of Cape

Hatteras Lighthouse, Buxton, NC) northward to the U.S./Canada border. The Council prepared the FMP under the authority of the Magnuson-Stevenson Act, 16 U.S.C. 1801 *et seq.* Regulations implementing the FMP appear at 50 CFR part 648, subparts A (general provisions), G (summer flounder), H (scup), and I (black sea bass). General regulations governing U.S. fisheries also appear at 50 CFR part 600. States manage summer flounder within 3 nautical miles of their coasts, under the Commission's plan for summer flounder, scup, and black sea bass. The Federal regulations govern vessels fishing in the exclusive economic zone (EEZ), as well as vessels possessing a Federal fisheries permit, regardless of where they fish.

The regulations outline the process for specifying the annual catch limits for the summer flounder, scup, and black sea bass commercial and recreational fisheries, as well as other management measures (*e.g.*, mesh requirements, minimum fish sizes, gear restrictions, possession restrictions, and area restrictions) for these fisheries. The measures are intended to achieve the annual targets set forth for each species in the FMP, specified either as an F or an exploitation rate (*i.e.*, the proportion of fish available at the beginning of the year that may be removed by fishing during the year). Once the catch limits are established, they are divided into quotas based on formulas contained in the FMP. Detailed background information regarding the status of the summer flounder, scup, and black sea bass stocks and the development of the 2009 specifications for these fisheries

was provided in the proposed specifications (73 FR 63934; October 28, 2008). That information is not repeated here.

NMFS will establish the 2009 recreational management measures for summer flounder, scup, and black sea bass by publishing proposed and final rules in the **Federal Register** at a later date, following receipt of the Council's recommendations as specified in the FMP.

Summer Flounder

This final rule implements the specifications contained in the October 28, 2008, proposed rule—a summer flounder Total Allowable Landings (TAL) of 18.45 million lb (8,368 mt) for 2009. This TAL has a 63-percent probability of constraining fishing mortality below the management target of $F_{40\text{ percent}}=0.255$ and a 97-percent probability of constraining fishing mortality below the overfishing threshold of $F_{\text{MSY}}=F_{35\text{ percent}}=0.310$. In recent years, NMFS has implemented summer flounder TALs that contained a 75-percent probability of constraining fishing mortality below the level (*i.e.*, F_{REBUILD}) expected to achieve the biomass target (*i.e.*, B_{MSY}) by January 1, 2013, to ensure that the Magnuson-Stevens Act rebuilding program is satisfied. The 2009 TAL has an 83-percent probability of constraining fishing mortality below $F_{\text{REBUILD}}=0.274$ level. Furthermore, for 2009, the TAL had been established using a management target that is lower than F_{REBUILD} (*i.e.*, $F_{40\text{ percent}}$ (management target) $< F_{\text{REBUILD}} < F_{\text{MSY}}$ (overfishing threshold)), thereby providing a greater

probability that the 2009 fishing mortality objective will not be exceeded and the required stock rebuilding will occur. This TAL setting approach also satisfies a 2000 Federal Court Order (*Natural Resources Defense Council v. Daley*, Civil No. 1:99 CV 00221 (JLG)) which requires the annual summer flounder TAL to have at least a 50-percent probability of success.

Three research projects that would utilize the full summer flounder research set-aside (RSA) of 553,500 lb (251 mt) have been conditionally selected by NMFS and are currently awaiting notice of award. If a proposed project is not approved by the NOAA Grants Office, the research quota associated with the disapproved proposal will be restored to the summer flounder TAL through publication in the **Federal Register**. After deducting the 2009 RSA, the TAL is divided into a commercial quota of 10,737,900 lb (4,871 mt) and a recreational harvest limit of 7,158,600 lb (3,247 mt).

Consistent with the revised quota setting procedures for the FMP (67 FR 6877, February 14, 2002), summer flounder overages are determined based upon landings for the period January–October 2008, plus any previously unaccounted for overages from January–December 2007. Table 1 summarizes, for each state, the commercial summer flounder percent shares as outlined in § 600.100(d)(1)(I), the resultant 2009 commercial quota (both initial and less the RSA), the quota overages as described above, and the final adjusted 2009 commercial quota less the RSA.

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TABLE 1. FINAL STATE-BY-STATE COMMERCIAL SUMMER FLOUNDER ALLOCATIONS FOR 2009

State	Percent Share	Initial Quota		Initial Quota, less RSA		2008 Quota Overages (through 10/31/08) ¹		Adjusted Quota, less RSA	
		lb	kg	lb	kg	lb	kg	lb	kg
ME	0.04756	5,265	2,388	5,107	2,317	0	0	5,107	2,317
NH	0.00046	51	23	49	22	0	0	49	22
MA	6.82046	755,025	342,479	732,374	322,205	29,760	13,499	702,614	318,700
RI	15.68298	1,736,106	787,498	1,684,023	763,873	0	0	1,684,023	763,873
CT	2.25708	249,859	113,336	242,363	109,936	0	0	242,363	109,936
NY	7.64699	846,522	383,982	821,126	372,463	0	0	821,126	372,463
NJ	16.72499	1,851,456	839,821	1,795,913	814,626	0	0	1,795,913	814,626
DE	0.01779	1,969	893	1,910	866	56,621	25,683	-54,711	-24,816
MD	2.03910	225,728	102,390	218,957	99,319	0	0	218,957	99,319
VA	21.31676	2,359,765	1,070,390	2,288,972	1,038,278	0	0	2,288,972	1,038,278
NC	27.44584	3,038,254	1,378,152	2,947,107	1,336,808	0	0	2,947,107	1,336,808
Total ²	100.00	11,070,001	5,021,353	10,737,901	4,870,712	86,381	41,514	10,706,231	4,856,265

¹ 2008 quota overage is determined through comparison of landings for January through October 2008, plus any landings in 2007 in excess of the 2007 quota (that were not previously addressed in the 2008 specifications) for each state. For Delaware, includes continued repayment of overharvest from 2008 and previous years.

² Total quota is the sum of all states having allocation. A state with a negative number has a 2009 allocation of zero (0). Kilograms are as converted from pounds and may not necessarily add due to rounding.

The Commission has established a system whereby 15 percent of each state's quota may be voluntarily set aside each year to enable vessels to land an incidental catch allowance after the directed fishery in a state has been closed. The intent of the incidental catch set-aside is to reduce discards by allowing fishermen to land summer flounder caught incidentally in other fisheries during the year, while ensuring that the state's overall quota is not exceeded. These Commission set-asides are not included in these 2009 final summer flounder specifications because NMFS does not have authority to establish such subcategories.

Delaware Summer Flounder Closure

Table 1 indicates that, for Delaware, the amount of the 2008 summer flounder quota coverage (inclusive of overharvest from previous years) is greater than the amount of commercial quota allocated to Delaware for 2009. As a result, there is no quota available for 2009 in Delaware. The regulations at § 648.4(b) provide that Federal permit holders, as a condition of their permit, must not land summer flounder in any state that the Administrator, Northeast Region, NMFS (Regional Administrator), has determined no longer has commercial quota available for harvest. Therefore, effective January 1, 2009, landings of summer flounder in Delaware by vessels holding commercial Federal summer flounder fisheries permits are prohibited for the 2009 calendar year, unless additional quota becomes available through a quota transfer and is announced in the **Federal Register**. Federally permitted dealers are advised that they may not purchase summer flounder from federally permitted vessels that land in Delaware for the 2009 calendar year, unless additional quota becomes available through a transfer, as mentioned above.

Scup

This final rule implements the least restrictive (*i.e.*, highest associated harvest levels) analyzed by the Council. The Council recommended, and NMFS published in the October 28, 2008, proposed rule, an 11.70-million-lb (5,339-mt) scup Total Allowable Catch (TAC) and a 7.34-million-lb (3,329-mt) scup TAL. The rationale for so doing was that scup are under a rebuilding plan and, at the time the Council met in August, the best available information

indicated that scup rebuilding was behind the established rebuilding schedule. During the interim between the Council recommending a 2009 TAC and TAL for scup, the Northeast Fisheries Science Center (NEFSC) convened a Data Poor Stocks Working Group (DPWG) to review biological reference points for scup. The peer review body of the DPWG has preliminarily indicated that the revised biological reference points, the modeling framework used to generate those reference points, and resultant change in stock status are acceptable, now represent the best available information, and should be utilized to craft management advice. While the final peer review report will not be available until late January or early February 2009, NMFS is implementing the least restrictive/highest scup TAC/TAL alternative analyzed by the Council as the updated stock status information resulting from the DPWG indicate the scup stock status has improved substantially and is rebuilt (*i.e.*, now above the revised rebuilding biomass target). Amendment 14 to the FMP established a scup rebuilding plan based on a fixed $F = 0.10$ approach. During the 2009 specification development, the Council considered establishing catch levels derived using the $F = 0.10$ approach but selected a more precautionary TAC and TAL because the information available at the time indicated that scup were behind the rebuilding schedule. Because scup are no longer considered to be behind schedule, the additional precaution recommended by the Council is no longer necessary. NMFS considers the $F = 0.10$ approach consistent with the intent of the FMP pending the release of the final DPWG report. When final reports are issued for the DPWG and scup stock status is officially updated using the revised biological reference points, NMFS may take additional action to further modify the 2009 scup specifications.

This rule implements a 15.54-million-lb (5,796-mt) scup TAC and an 11.18-million-lb (4,170-mt) scup TAL. The TAC is divided into commercial (78 percent) and recreational (22 percent) allocations, in accordance with the FMP; the respective discard estimates are then subtracted to yield the preliminary TAL. NMFS is not altering the RSA amount contained in the proposed rule because projects utilizing

that amount have already been subject to NOAA Grants Office review and preliminary approval. Therefore, after deducting 220,200 lb (100 mt) of RSA for the three conditionally selected research projects, the initial TAL is a commercial quota of 8,373,848 lb (3,123 mt) and a recreational harvest limit of 2,585,952 lb (965 mt). If a proposed project is not approved by the NOAA Grants Office, the research quota associated with the disapproved proposal will be restored to the scup TAL through publication in the **Federal Register**.

The commercial TAC, discards, and TAL (commercial quota) are allocated on a percentage basis to three quota periods, as specified in the FMP: Winter I (January–April)—45.11 percent; Summer (May–October)—38.95 percent; and Winter II (November–December)—15.94 percent. The recreational harvest limit is allocated on a coastwide basis. Consistent with the revised quota setting procedures established for the FMP (67 FR 6877, February 14, 2002), scup overages are determined based upon landings for the Winter I and Summer 2008 periods, plus any previously unaccounted for landings from the 2007 Winter II period (January–December 2007). Table 2 presents the final 2009 commercial scup quota for each period and the reported 2008 landings for the 2008 Winter I and Summer periods. There was no overage of the Winter I quota; however, an overage of 328,795 lb (149 mt) occurred during the Summer period. An additional 2,085 lb (946 kg) that was previously unaccounted for in the 2008 specifications quota adjustments for the scup Summer period will be added to the 2008 overage, resulting in a total 2009 Summer period quota deduction of 330,880 lb (150 mt).

On August 11, 2008 (73 FR 46554), NMFS announced a transfer of unharvested quota from the Winter I to the Winter II 2008 quota period. Per the quota accounting procedures, after June 30, 2009, NMFS will compile all available landings data for the 2008 Winter II quota period and compare the landings to the 2008 Winter II quota period allocation, as adjusted by the aforementioned transfer. Any overages will be determined, and deductions, if needed, will be made to the Winter II 2009 allocation and published in the **Federal Register**.

TABLE 2. SCUP PRELIMINARY 2008 COMMERCIAL LANDINGS BY QUOTA PERIOD

Quota Period	2008 Quota		Reported 2008 Landings through 10/31/08		Preliminary Overages as of 10/31/08 ¹	
	lb	mt	lb	mt	lb	mt
Winter I	2,388,611	1,083	2,309,508	1,048	0	0
Summer	1,437,588	652	1,766,353	801	330,880	150
Winter II	Overage adjustment, if necessary, occurs in 2009					
Total	4,670,204	2,118	4,075,861	1,849	N/A	N/A

¹Includes additional 2007 overage of 2,085 lb (946 kg) previously unaccounted for in 2008 specifications and

Table 3 presents the commercial scup percent share, 2009 TAC, projected discards, 2009 initial quota (with and without the RSA deduction), overage deductions (as necessary), and initial possession limits, by quota period.

This final rule continues the status quo Winter I period (January–April) per-trip possession limit of 30,000 lb (13.6 mt), and a Winter II period (November–December) initial per-trip possession limit of 2,000 lb (907 kg). The Winter I

per-trip possession limit will be reduced to 1,000 lb (454 kg) when 80 percent of the commercial quota allocated to that period is projected to be harvested.

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TABLE 3. INITIAL COMMERCIAL SCUP QUOTA ALLOCATIONS FOR 2009 BY QUOTA PERIOD

Quota Period	Per-cent Share	Total Allowable Catch		Discards		Initial Quota		Initial Quota less Overages (through 10/31/2008) ¹		Adjusted Quota less Overages and RSA		Possession Limits (Per Trip) ²	
		lb	mt	lb	mt	lb	mt	lb	mt	lb	mt	lb	kg
Winter I	45.11	5,467,873	2,480	1,614,938	732	3,852,935	1,749	N/A	N/A	3,777,443	1,713	30,000	13,608
Summer	38.95	4,721,207	2,142	1,394,410	632	3,326,797	1,509	2,995,917	1,853	2,930,733	1,329	N/A	N/A
Winter II	15.94	1,932,119	876	570,652	259	1,361,467	618	N/A	N/A	1,334,791	605	2,000	907
Total ³	100.0	12,121,200	5,498	3,580,000	1,623	8,541,200	3,842	N/A	N/A	8,373,848	3,798	N/A	N/A

¹See Table 1 for explanation of overages.

²The Winter I possession limit will drop to 1,000 lb (454 kg) upon attainment of 80 percent of that period's allocation. The Winter II possession limit may be adjusted (in association with a transfer of unused Winter I quota to the Winter II period) via notification in the Federal Register.

³ Metric tons are as converted from pounds and may not necessarily add due to rounding.

N/A=Not applicable.

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Consistent with the unused Winter I commercial scup quota rollover provisions at § 648.120(a)(3), this final rule maintains the Winter II possession

limit-to-rollover amount ratios that were in place since the 2007 fishing year, as shown in Table 4. The Winter II possession limit will increase by 1,500

lb (680 kg) for each 500,000 lb (227 mt) of unused Winter I period quota transferred, up to a maximum possession limit of 8,000 lb (3,629 kg).

TABLE 4. POTENTIAL INCREASE IN WINTER II POSSESSION LIMITS BASED ON THE AMOUNT OF SCUP ROLLED OVER FROM WINTER I TO WINTER II PERIOD

Initial Winter II Possession Limit		Rollover from Winter I to Winter II		Increase in Initial Winter II Possession Limit		Final Winter II Possession Limit after Rollover from Winter I to Winter II	
lb	kg	lb	mt	lb	kg	lb	kg
2,000	907	0-499,999	0-227	0	0	2,000	907
2,000	907	500,000-999,999	227-454	1,500	680	3,500	1,588
2,000	907	1,000,000-1,499,999	454-680	3,000	1,361	5,000	2,268
2,000	907	1,500,000-1,999,999	680-907	4,500	2,041	6,500	2,948
2,000	907	2,000,000-2,500,000	907-1,134	6,000	2,722	8,000	3,629

Black Sea Bass

This final rule implements the specification contained in the October 28, 2008, proposed rule: A 2.3-million-lb (1,043-mt) black sea bass TAL. The FMP specifies that the annual TAL is allocated 49 percent to the commercial sector and 51 percent to the recreational sector. After deducting 69,000 lb (31 mt) of RSA for the three conditionally selected research projects, the TAL is divided into a commercial quota of 1,093,190 lb (456 mt) and a recreational harvest limit of 1,137,810 lb (516 mt).

If a proposed project is not approved by the NOAA Grants Office, the research quota associated with the disapproved proposal will be restored to the black sea bass TAL through publication in the **Federal Register**. Consistent with the revised quota setting procedures for the FMP, black sea bass overages are determined based upon landings for the period January–September 2008, plus any previously unaccounted for landings from January–December 2007. There were no overages for either period; thus, no overage deduction adjustment to the 2009 commercial quota is necessary.

Comments and Responses

NMFS received three comments during the comment period for the October 28, 2008, proposed rule. One commenter supported the proposed summer flounder TAL and two commenters supported the RSA projects preliminarily approved for 2009.

Comment 1: An association that advocates for recreational fisheries objected to the RSA project approval process. This commenter stated support

for the intent of the RSA program and stated no specific objection to the 2009 preliminarily approved projects.

Response: The RSA approval process is not part of the specification rulemaking process. NMFS and the Council work cooperatively each year to identify research priorities and to determine which submitted proposals should be selected for eventual RSA funding through the NOAA Grants award process. The commenter's letter has been forwarded to both the Northeast Fisheries Science Center (NEFSC) and the Council's Research Steering Committee, as these groups are involved in the annual RSA project selection process and are better suited to address the concerns raised.

Comment 2: One commenter stated that a benchmark assessment is needed for black sea bass and that the current trawl index utilized is inadequate for determining exploitable biomass.

Response: The most recent black sea bass stock assessment was conducted in 2006 as part of the 43rd Northeast Regional Stock Assessment Workshop (SAW); this assessment was rejected by the independent peer review body because it did not provide an adequate basis to evaluate stock status against the biological reference points. The peer reviewers did not recommend any other reference points; thus, NMFS has continued use of the biological reference points contained in the FMP as the best available scientific information. This includes the index-based assessment approach utilized to evaluate the status of the stock for management purposes.

NMFS agrees that black sea bass is a data-poor stock and that the biology of

the fish makes assessments challenging. Currently, staff from the NEFSC, NMFS Northeast Regional Office, Council, Commission, and academia are conducting a series of working group meetings for data-poor stocks, including black sea bass, that may yield revised biological reference points. Peer-review of the working group recommendations will occur in December 2008 and final results are expected in late January or early February 2009.

Comment 3: One commenter supported the scup TAC, but disagreed with the commercial discard estimate utilized to derive the scup TAL.

Response: The discard estimates provided by the NEFSC, derived from at-sea observer data, are the only data available to assess the magnitude of scup discards in commercial fisheries. As such, the estimates constitute the best available scientific information, consistent with National Standard 2.

The Council and the NEFSC work cooperatively to prioritize observer coverage through the annual Standard Bycatch Reporting Methodology (SBRM) consultation process; however, observer resources are limited at this time. In addition, a working group has been formed that is composed of personnel from both Northeast regional fishery management councils and NMFS to explore additional observer funding options, including, but not limited to, cost recovery, industry funding, and alternative coverages such as video monitoring, to increase the level of observer coverage in some Northeast Region fisheries.

Comment 4: One commenter requested that the summer flounder

recreational fishery be managed separately from the commercial fishery with each having separate Annual Catch Limits (ACLs) and Accountability Measures (AMs). Specifically, the commenter requested that any recreational fishery overage be taken from the following year's recreational harvest limit as a pound-for-pound overage repayment.

Response: Under the current FMP structure, the commercial fishery has an annual quota that is 60 percent of the overall TAL. The recreational fishery receives 40 percent of the TAL as a recreational harvest limit. An amendment to the FMP would be required to enact the commenter's request. The Council is currently beginning development of an amendment to address ACLs and AMs for the FMP. The Council may consider having separate measures for commercial and recreational fishing modes and may also consider mode-specific AMs, such as overage repayment.

Comment 5: One commenter stated that overages in the summer flounder recreational fishery, wherein the annual recreational harvest limit is exceeded, compromises NMFS's ability to estimate probabilities for a given TAL's success. The commenter further suggests that this makes the probabilities provided inconsistent with the best available scientific information.

Response: NMFS agrees that when the basic assumptions involving the probability calculations are violated, the probability for achieving the annual management target (*i.e.*, success) can be compromised. It is for this reason that NMFS has been implementing only annual TALs with a higher than 50-percent probability of success when stock rebuilding stalled in the mid-2000s.

The 2008 summer flounder benchmark assessment conducted by the Southern Demersal Working Group (SDWG) recommended a management target (F_{40} percent) and threshold (F_{35} percent) approach. The rationale for this approach is that setting an ACL on a target allows for some amount of imprecision wherein the catch may result in an F above or below the target roughly 50 percent of the time. However, the catch should still remain below the threshold level at which the stock experiences overfishing. The Council agreed with this recommendation from the peer-reviewed stock assessment and set the 2009 TAL using the F target, creating a buffer between the 2009 projected F and the overfishing level F of the F threshold.

In addition, the Council acknowledged that there is some degree of imprecision in managing the summer flounder fishery and elected to recommend to NMFS a TAL that is lower than the SSC's recommendation for Acceptable Biological Catch (ABC). The reduction from the recommended ABC of 19.5 million lb (8,845 mt) to 18.45 million lb (8,369 mt) was deliberate, and designed to provide a buffer for uncertainties such as exceeding the recreational harvest limit. NMFS agrees that utilization of an F target approach in TAL setting, paired with the additional risk-averse approach of reducing TAL from ABC, should provide a very high likelihood that overfishing will not occur in 2009.

Specific management measures designed to constrain recreational harvest to the 2009 recreational harvest limit will be developed by the Council and Commission in December. NMFS agrees that it is of paramount importance that such measures be sufficient to ensure that the recreational harvest limit is not exceeded.

Classification

The Administrator, Northeast Region, NMFS, determined that this final rule is necessary for the conservation and management of the summer flounder, scup, and black sea bass fisheries and that it is consistent with the Magnuson-Stevens Act and other applicable laws.

The Assistant Administrator for Fisheries, NOAA, finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delayed effectiveness period for this rule, to ensure that the final specifications are in place on January 1, 2009. This action establishes specifications (*i.e.*, annual quotas) for the summer flounder, scup, and black sea bass fisheries and possession limits for the commercial scup fishery.

Preparation of the proposed rule was dependent on the submission of the EA/RIR/IRFA in support of the specifications which is developed by the Council. This document was received by NMFS in the last days of September 2008. Documentation in support of the Council's recommended specifications is required for NMFS to provide the public with information from the environmental and economic analyses as required in rulemaking. The proposed rule published on October 28, 2008, with a 15-day comment period ending November 12, 2008. Publication of the adjusted summer flounder quota at the start of the fishing year that begins January 1, 2009, is required by the order of Judge Robert Doumar in *North Carolina Fisheries Association v. Daley*.

If the 30-day delay in effectiveness were to be required, the lack of effective quota specifications on January 1, 2009, would present significant difficulties to both NMFS and individual states who manage these species cooperatively through the Commission. The summer flounder, scup, and black sea bass fisheries are all expected, based on historic participation and harvest patterns, to be very active at the start of the fishing season in 2009. Individual states would be unable to set commercial possession and/or trip limits which apportion the catch over the entirety of the calendar year. NMFS would be unable to control harvest in any way as there would be no quotas in place for any of the three species until the regulations are effective. NMFS would be unable to control harvest or close the fishery should landings exceed the quotas. In addition, the Delaware summer flounder fishery would be open for fishing but in a negative quota situation. All of these factors would result in a race for fish wherein uncontrolled landings would occur. Disproportionately large harvest occurring within the first weeks of 2009 would have distributional effects on other quota periods and would disadvantage some gear sectors or owners and operators of smaller vessels that typically fish later in the fishing season. There is no historic precedent by which to gauge the magnitude of harvest that might occur should quotas for these three species not be in place during the first weeks of 2009. It is reasonable to conclude that the commercial fishing fleet possesses sufficient capacity to exceed the established quotas for these three species before the regulations would become effective, should quotas not be in place on January 1, 2009. Should this occur, the stock rebuilding objectives for all three species rebuilding plans would be compromised.

This final rule has been determined to be not significant for purposes of Executive Order 12866 because this action contains no implementing regulations.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This FRFA was prepared pursuant to 5 U.S.C. 604(a), and incorporates the IRFA, a summary of the significant issues raised by the public comments in response to the IRFA, NMFS's responses to those comments, and a summary of the analyses completed to support the action. A copy of the EA/RIR/IRFA is available from the Council (see **ADDRESSES**).

The preamble to the proposed rule included a detailed summary of the analyses contained in the IRFA, and that discussion is not repeated here.

Final Regulatory Flexibility Analysis

Statement of Objective and Need

A description of the reasons why this action is being taken, and the objectives of and legal basis for this final rule are contained in the preambles to the proposed rule and this final rule and are not repeated here.

Summary of Significant Issues Raised in Public Comments

No changes to the proposed rule were required to be made as a result of public comments as most of the comments did not address specific issues in this rulemaking or the economic analyses summarized in the IRFA. For a summary of the comments received, and the responses thereto, refer to the "Comments and Responses" section of this preamble.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

The categories of small entities likely to be affected by this action include commercial and charter/party vessel owners holding an active Federal commercial or charter/party permit for summer flounder, scup, or black sea bass, as well as owners of vessels that fish for any of these species in state waters. The Council estimates that the 2009 quotas could affect 2,263 vessels that held a Federal summer flounder, scup, and/or black sea bass permit in 2007, the most recent year for which complete permit data exists. The more immediate impact of this final rule will likely be felt by the 891 vessels that actively participated (*i.e.*, landed these species) in these fisheries in 2007.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

No additional reporting, recordkeeping, or other compliance requirements are included in this final rule.

Description of the Steps Taken to Minimize Economic Impact on Small Entities

Specification of commercial quotas and possession limits is constrained by the conservation objectives set forth in the FMP and implemented at 50 CFR part 648 under the authority of the Magnuson-Stevens Act. Economic impacts of reduced quota specifications, which reduce the number of fish that may be taken by participants of both

commercial and recreational fisheries, may be offset by adjustments to such measures as commercial fish sizes, changes to mesh sizes, gear restrictions, or possession and trip limits that may increase efficiency or value of the fishery. For 2009, no such adjustments were recommended by the Council; therefore, this final rule contains no such measures. Therefore, the economic impact analysis of the action is evaluated solely on the different levels of quota specified in the alternatives. The ability of NMFS to minimize economic impacts for this action is constrained to approving quota levels that provide the maximum availability of fish while still ensuring that the required objectives and directives of the FMP, its implementing regulations, and the Magnuson-Stevens Act, particularly the stock rebuilding requirements of all three species rebuilding plans, are met.

The economic analysis for the 2009 specification assessed the impacts for quota alternatives that achieve the aforementioned objectives. The no action alternative, wherein no quotas are established for 2009, was excluded from analysis because it is not consistent with the goals and objectives of the FMP and the Magnuson-Stevens Act. Implementation of the no action alternative in 2009 would substantially complicate the approved management programs for these three species. NMFS is required under the FMP's implementing regulations to specify and implement a TAL (and TAC for scup) for these fisheries on an annual basis. The no action alternative would result in no TAL (and no scup TAC) for 2009, and would likely result in overfishing of the resources and substantially compromise the stock rebuilding and/or mortality objectives for each species.

Furthermore, Alternative 2 from the Council's analysis contains the most restrictive TAL options (*i.e.*, the lowest catch levels). While this alternative would achieve the required objectives for all three species, it carries the highest potential negative impact on small entities in the form of foregone fishing opportunity. Alternative 2 was not preferred by the Council or NMFS because other alternatives considered have lower impacts on small entities while achieving the stated objectives of the 2009 specification process.

Alternative 3 (least restrictive quotas; highest catch levels) would produce the smallest impact on small entities. For summer flounder, the Alternative 3 TAL was consistent with the Council's SSC recommendation for ABC. The Council expressed concerns that setting the TAL equal to ABC would not provide any leeway for implementation imprecision,

and that the summer flounder stock has only 4 years remaining to achieve the rebuilding biomass objective. NMFS agrees that setting TAL equal to ABC while the stock is under a rebuilding plan and not yet rebuilt is not the most prudent course of action. For black sea bass, the Alternative 3 measures would retain the status quo. The black sea bass TAL under this alternative would be inconsistent with the rebuilding plan because the resulting landings level would be higher than permitted under the rebuilding plan's fishing mortality calculation. Therefore, while the summer flounder and black sea bass TALs of Alternative 3 may mitigate economic impacts on small entities by providing greater harvest opportunities, both the Council and NMFS find the resulting harvest levels to be inconsistent with the goals and objectives of the annual specifications and stock rebuilding programs.

Through this final rule, NMFS implements the summer flounder and black sea bass TALs contained in Alternative 1, the Council's preferred alternatives, which consist of the quota alternatives with an intermediate level economic impacts to small entities when compared to Alternatives 2 and 3 for those two species. NMFS also implements scup TAL Alternative 3, the least restrictive alternative analyzed by the Council, for the reasons outlined in the preamble to this rule (*i.e.*, change in stock status resulting from the DPWG findings in the interim months between the Council's recommendation and this final rule). Scup TAL Alternative 3 has the lowest economic impact to small entities when compared to Alternatives 1 and 2. Relative to 2008, the 2009 commercial quotas and recreational harvest measures in this action would result in the following TAL changes for the commercial and recreational sectors:

- (1) A 17.0-percent increase for summer flounder;
- (2) a 52.3-percent increase for scup; and
- (3) a 52.0-percent decrease for black sea bass.

TAL Alternatives 1 for summer flounder and black sea bass were selected because they satisfy NMFS's obligation to implement specifications that are consistent with the goals, objectives, and requirements of the FMP, its implementing regulations, and the Magnuson-Stevens Act. TAL Alternative 3 for scup was selected because it allows for an increase of the 2009 specifications above the level contained in the Council's recommended scup Alternative 1 and endorsed by NMFS in the proposed rule in reaction to the most recent peer-

reviewed information regarding stock status. This stock status information was not available when the Council deliberated 2009 TAL options in August, nor was the information available when NMFS published the proposed rule in October. The DPWG concluded its work in early December. As previously stated in the preamble, when final DPWG reports regarding stock are available in early 2009, NMFS may take additional action to modify the 2009 scup specifications implemented by this final rule. The Alternative 1 TAL for summer flounder is sufficiently risk-averse, providing a high probability that the rebuilding F rate and an even higher probability that the overfishing threshold (F_{35 percent}) will not be exceeded in 2009. Given the regulatory and statutory requirements, Alternative 1 minimizes, to the extent practicable, the economic impacts on small entities that participate in the summer flounder fishery. The black sea bass quota in Alternative 1 was selected because it is consistent with the TAL calculation methodology of the rebuilding plan and results in a measure that will adequately constrain harvest in 2009, and provide continued rebuilding of the overfished stock. The scup TAL contained in Alternative 3 provides the maximum harvest level analyzed by the Council and is consistent with the revised stock status information verbally endorsed for management advice by the DPWG peer review panel. In addition, the scup Alternative 3 TAL remains consistent with F rate contained in the Amendment 14 scup rebuilding plan, which remains effective until formal advice is conveyed in the final DPWG reports.

The revenue decreases associated with the RSA program are expected to be minimal, and are expected to yield important benefits associated with improved fisheries data. It should also be noted that fish harvested under the RSA program would be sold, and the profits would be used to offset the costs of research. As such, total gross revenues to the industry will not decrease substantially, if at all, as a result of this final rule authorizing RSA for 2009.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall

explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide will be sent to all holders of Federal permits issued for the summer flounder, scup, and black sea bass fisheries. In addition, copies of this final rule and guide (*i.e.*, permit holder letter) are available from NMFS (see **ADDRESSES**) and at the following Web site: <http://www.nero.noaa.gov>.

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

Dated: December 24, 2008.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. E8-31236 Filed 12-31-08; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106673-8011-02]

RIN 0648-XM47

Fisheries of the Exclusive Economic Zone Off Alaska; Inseason Adjustment to the 2009 Bering Sea Pollock Total Allowable Catch Amount

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

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the 2009 total allowable catch amount (TAC) for the Bering Sea pollock fishery. This action is necessary because NMFS has determined this TAC is incorrectly specified. This action will ensure the Bering Sea pollock TAC does not exceed the appropriate amount based on the best available scientific information for pollock in the Bering Sea subarea. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP).

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), December 29, 2008, through 2400 hrs, A.l.t., December 31, 2009, unless otherwise modified or superceded through publication of a notification in the **Federal Register**.

Comments must be received at the following address no later than 4:30 p.m., A.l.t., December 29, 2008.

ADDRESSES: Send comments to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by "RIN 0648-XM47," by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal website at <http://www.regulations.gov>.

- Mail: P. O. Box 21668, Juneau, AK 99802.

- Fax: (907) 586-7557.

- Hand delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats only.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (BSAI) according to the FMP prepared by the North Pacific Fishery Management Council (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 2009 pollock TAC in the Bering Sea subarea was set at 1,000,000 metric tons (mt) by the 2008 and 2009 harvest specification for groundfish in the BSAI (73 FR 10160, February 26, 2008).

In December 2008, the Council recommended a 2009 pollock TAC of 815,000 mt for the Bering Sea subarea. This amount is less than the 1,000,000 mt established by the final 2008 and 2009 harvest specification for groundfish in the BSAI (73 FR 10160, February 26, 2008). The TAC recommended by the Council is based on the Stock Assessment and Fishery Evaluation report (SAFE), dated November 2008, which NMFS has

determined is the best available scientific information for this fishery.

Steller sea lions occur in the same location as the pollock fishery and are listed as endangered under the Endangered Species Act (ESA). Pollock is a principal prey species for Steller sea lions in the BSAI. The seasonal apportionment of pollock harvest is necessary to ensure the groundfish fisheries are not likely to cause jeopardy

of extinction or adverse modification of critical habitat for Steller sea lions. The regulations at § 679.20(a)(5)(i)(A) specify how the pollock TAC shall be apportioned.

In accordance with § 679.25(a)(2)(i)(B), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that, based on the November 2008 SAFE report for this fishery, the current Bering

Sea pollock TAC is incorrectly specified. Consequently, the Regional Administrator is adjusting the 2009 pollock TAC to 815,000 mt in the Bering Sea subarea.

Pursuant to § 679.20(a)(5), Table 3 of the final 2008 and 2009 harvest specifications for groundfish in the BSAI (73 FR 10160, February 26, 2008) is revised for the 2009 pollock TACs consistent with this adjustment.

TABLE 3—2008 AND 2009 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA)¹

[Amounts are in metric tons]

Area and sector	2008 Allocations	2008 A season ¹		2008 B season ¹	2009 Allocations	2009 A season ¹		2009 B season ¹
		A season DFA	SCA harvest limit ²	B season DFA		A season DFA	SCA harvest limit ²	B season DFA
Bering Sea subarea	1,000,000	n/a	n/a	n/a	815,000	n/a	n/a	n/a
CDQ DFA	100,000	40,000	28,000	60,000	81,500	32,600	22,820	48,900
ICA ¹	31,500	n/a	n/a	n/a	25,673	n/a	n/a	n/a
AFA Inshore	434,250	173,700	121,590	260,550	353,914	141,566	99,096	212,348
AFA Catcher/Processors ³	347,400	138,960	97,272	208,440	283,131	113,252	79,277	169,879
Catch by C/Ps	317,871	127,148	n/a	190,723	259,065	103,626	n/a	155,439
Catch by CVs ³	29,529	11,812	n/a	17,717	24,066	9,626	n/a	14,440
Unlisted C/P Limit ⁴	1,737	695	n/a	1,042	1,416	566	n/a	849
AFA Motherships	86,850	34,740	24,318	52,110	70,783	28,313	19,819	42,470
Excessive Harvesting Limit ⁵	151,988	n/a	n/a	n/a	123,870	n/a	n/a	n/a
Excessive Processing Limit ⁶	260,550	n/a	n/a	n/a	212,348	n/a	n/a	n/a
Total Bering Sea DFA	868,500	347,400	243,180	521,099	707,829	283,130	198,192	424,697
Aleutian Islands subarea ¹	19,000	n/a	n/a	n/a	19,000	n/a	n/a	n/a
CDQ DFA	1,900	760	n/a	1,140	1,900	760	n/a	1,140
ICA	1,600	800	n/a	800	1,600	800	n/a	800
Aleut Corporation	15,500	15,500	n/a	0	15,500	15,500	n/a	0
Bogoslof District ICA ⁷	10	n/a	n/a	n/a	10	n/a	n/a	n/a

¹Pursuant to § 679.20(a)(5)(i)(A), the Bering Sea subarea pollock, after subtraction for the CDQ DFA (10 percent) and the ICA (3.5 percent), is allocated as a DFA as follows: inshore sector – 50 percent, catcher/processor sector (C/P) – 40 percent, and mothership sector – 10 percent. In the Bering Sea subarea, 40 percent of the DFA is allocated to the A season (January 20–June 10) and 60 percent of the DFA is allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(2)(i) and (ii), the annual AI pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second the ICA (1,600 mt), is allocated to the Aleut Corporation for a directed pollock fishery. In the AI subarea, the A season is allocated 40 percent of the ABC and the B season is allocated the remainder of the directed pollock fishery.

²In the Bering Sea subarea, no more than 28 percent of each sector's annual DFA may be taken from the SCA before April 1. The remaining 12 percent of the annual DFA allocated to the A season may be taken outside of SCA before April 1 or inside the SCA after April 1. If less than 28 percent of the annual DFA is taken inside the SCA before April 1, the remainder will be available to be taken inside the SCA after April 1.

³Pursuant to § 679.20(a)(5)(i)(A)(4), not less than 8.5 percent of the DFA allocated to listed catcher/processers shall be available for harvest only by eligible catcher vessels delivering to listed catcher/processers.

⁴Pursuant to § 679.20(a)(5)(i)(A)(4)(iii), the AFA unlisted catcher/processers are limited to harvesting not more than 0.5 percent of the catcher/processers sector's allocation of pollock.

⁵Pursuant to § 679.20(a)(5)(i)(A)(6), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

⁶Pursuant to § 679.20(a)(5)(i)(A)(7), NMFS establishes an excessive processing share limit equal to 30.0 percent of the sum of the non-CDQ pollock DFAs.

⁷The Bogoslof District is closed by the final harvest specifications to directed fishing for pollock. The amounts specified are for ICA only and are not apportioned by season or sector.

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 allow for harvests that exceed the appropriate allocations for pollock based on the best scientific information available. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 19, 2007, and additional

time for prior public comment would result in conservation concerns for the ESA-listed Steller sea lions.

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.

Under § 679.25(c)(2), interested persons are invited to submit written

comments on this action to the above address until January 13, 2008.

This action is required by § 679.22 and § 679.25 and is exempt from review under Executive Order 12866.

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

Dated: December 24, 2008.

Alan D. Risenhoover,

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

[FR Doc. E8-31224 Filed 12-29-08; 4:15 pm]

BILLING CODE 3510-22-S

Proposed Rules

Federal Register

Vol. 74, No. 1

Friday, January 2, 2009

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.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA-HQ-RCRA-2008-0329; FRL-8758-5]

RIN 2050-AG44

Identification of Non-Hazardous Materials That Are Solid Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advanced notice of proposed rulemaking (ANPRM).

SUMMARY: The Environmental Protection Agency (EPA or Agency) is seeking comment on which non-hazardous materials are or are not solid waste under the Resource Conservation and Recovery Act (RCRA). The Agency is also seeking comment on a number of specific questions concerning the meaning of "solid waste" under RCRA, as it applies to non-hazardous waste programs. We are issuing this ANPRM to assist the Agency in developing certain standards under sections 112 and 129 of the Clean Air Act (CAA). The meaning of "solid waste" as defined under RCRA is of particular importance since CAA section 129 states that the term "solid waste" shall have the meaning "established by the Administrator pursuant to [RCRA]."

DATES: Comments must be received on or before February 2, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2008-0329, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail*: Comments may be sent by electronic mail (e-mail) to: rcra-docket@epa.gov, Attention Docket ID No. EPA-HQ-RCRA-2008-0329. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail

system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

- *Fax*: Comments may be faxed to 202-566-9744, Attention Docket ID No. EPA-HQ-RCRA-2008-0329.

- *Mail*: Advanced Notice of Proposed Rulemaking—Identification of Non-Hazardous Materials That Are Solid Waste, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. Attention Docket ID No. EPA-HQ-RCRA-2008-0329.

- *Hand Delivery*: Deliver two copies of your comments to the Advanced Notice of Proposed Rulemaking—Identification of Non-Hazardous Materials That Are Solid Waste, EPA/DC, EPA West, Room 3334, and 1301 Constitution Ave., NW., Washington, DC 20460. Attention Docket ID No. EPA-HQ-RCRA-2008-0329. Such deliveries are only accepted during the docket's normal hours of operation (8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays), and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-RCRA-2008-0329. EPA's policy is that all comments received will be included in the public docket without change and may be made available online 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 <http://www.regulations.gov> or e-mail. The <http://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 <http://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 additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. We also request that interested parties who would like information they previously submitted to EPA to be considered as part of this action, identify the relevant information by docket entry numbers and page numbers.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. 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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the OSWER Docket, 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 OSWER Docket is 202-566-0270.

FOR FURTHER INFORMATION CONTACT: For questions regarding the development of this ANPRM, contact Michael Galbraith, Office of Solid Waste (5302P), U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0002, telephone (703) 605-0567, e-mail address: galbraith.michael@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Categories and entities potentially affected by this action include:

Generators		Users	
Major generator category	NAICS	Major boiler type and primary industry category	NAICS
Iron and Steel Mills	331111	<i>Industrial Boilers:</i>	
Scrap Tires	N/A	Food Manufacturing	311, 312
Passenger cars and trucks	326290	Pulp and Paper Mills	322
Other rubber product manufacturing		Chemicals and Allied Products	325
Logging	113310	Petroleum Refining	324
Sawmills and Wood Preservation	32111	Metals	331, 332
Veneer, Plywood, and Engineered Wood Product Manufacturing ..	32121	Other Manufacturing	313, 339, 321, 333, 336, 511, 326, 316, 327
Pulp, Paper, and Paperboard Mills	3221	<i>Commercial Boilers:</i>	
Cattle Ranching and Farming	1121	Office	813, 541, 921
Hog and Pig Farming	1122	Warehouse	421, 422
Poultry and Egg Production	1123	Retail	441, 445–454
Sheep and Goat Farming	1124	Education	611
Horses and Other Equine Production	112920	Public Assembly	624,
Crop Production	111	Lodging, Restaurant	721, 722
Support Activities for Crop Production	11511	Health Care Facilities	621
Food Manufacturing	311	Other	922140, others
Beverage and Tobacco Product Manufacturing	312	<i>Common Non-Manufacturing Boilers:</i>	
Construction of Buildings	236	Agriculture (crop & livestock production) ..	111, 112, 115
Site Preparation Contractors	238910	All Mining	212, 211
Landscaping Services	561730	Construction	235
Iron and Steel Mills	331111	<i>Other Boilers:</i>	
Fossil Fuel Electric Power Generation	221112	Electric Utility Boilers	221100
Cement Manufacturing	327310	Non HW Burning Cement Kilns	327310
Bituminous Coal and Lignite Surface Mining	212111		
Bituminous Coal Underground Mining	212112		
Anthracite Mining	212113		
Sewage Treatment Facilities	221320		
Solid Waste Landfill	562212		
Metal-casting industry	3115		
Glass and Glass Product Manufacturing	3272		
Packaging	32611		
Plastic manufacturers	325211		
Electrometallurgical Ferroalloy Product Manufacturing	331112		
Recycling services for degreasing solvents manufacturing	325998		
Solvent dyes manufacturing	325132		
Solvents made in petroleum refineries; and	324110		
Automotive repair and replacement shops	811111		

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be impacted by this action. This table lists examples of the types of entities of which EPA is aware that could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your facility, company, business, organization, etc., is affected by this action, you should examine the applicability criteria in this rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.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:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- 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.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

- Describe any assumptions and provide any technical information and/or data that you used.

- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- Provide specific examples to illustrate your concerns, and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

- Make sure to submit your comments by the comment period deadline identified.

II. Background

The United States Court of Appeals for the District of Columbia Circuit vacated and remanded two Agency rules promulgated under the CAA—The Commercial and Industrial Solid Waste Incineration (CISWI) definitions rule (“CISWI Definitions Rule”), issued under CAA section 129, and the Industrial Boilers Maximum Achievable Control Technology (MACT) standards rule (“Boilers Rule”), issued under CAA section 112. The court concluded that EPA erred by excluding units that combust solid waste for the purposes of energy recovery from the Definitions Rule and including such units in the Boilers Rule. In response to the court’s decision, EPA is preparing to establish new standards under CAA sections 112 and 129 for the various units subject to each section.

Congress added section 129 to the CAA in 1990 specifically to address emissions from solid waste combustion. CAA section 129 directs EPA to promulgate emission standards for “solid waste incineration units.” 42 U.S.C. 7429(a)(1). The term “solid waste incineration unit” is defined, in pertinent part, to mean “any facility which combusts any solid waste material from commercial or industrial establishments * * *” *Id.* at section 7429(g)(1). However, the CAA excludes the following types of units from classification as solid waste incineration units that are subject to the section 129 standards: (1) Incinerators or other units required to have a permit under section 3005 of RCRA; (2) materials recovery facilities (including primary and secondary smelters) which combust waste for the primary purpose of recovering metals; (3) qualifying small power production facilities, as defined in section 3(17)(C) of the Federal Power Act, or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power Act, which burn homogeneous waste (such as units which burn tires or used oil, but not

including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy or steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes, or (4) air curtain incinerators, provided that such incinerators only burn wood wastes, yard wastes and clean lumber and that such air curtain incinerators comply with the opacity limitations to be established by the Administrator by rule. CAA section 129 also states that the term “solid waste” shall have the meaning “established by the Administrator pursuant to the Solid Waste Disposal Act” *Id.* at 7429(g)(6).¹ RCRA defines the term “solid waste” to mean “* * * any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (86 Stat. 880), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923).” Section 1004 (27).

A. CISWI Rule/CISWI Definitions Rule/Boiler Rule

EPA fulfilled its statutory obligation under CAA section 129 when it promulgated a final rule setting forth performance standards and emission guidelines (EG) for Commercial and Industrial Solid Waste Incineration Units (referred to as the “CISWI Rule”). 65 FR 75338 (December 1, 2000). Under CAA section 129, the New Source Performance Standards (NSPS) and EG adopted for CISWI units must reflect the maximum degree of reduction in emissions of air pollutants that the Administrator determines is achievable, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements. This level of control is commonly referred to as MACT. The Administrator may also distinguish

among classes, types (including mass-burn, refuse-derived fuel, modular and other types of units), and sizes of units within a category in establishing such standards. *Id.* at 7429(a)(2).

NSPS apply to new stationary sources—that is, sources whose construction begins after the NSPS is proposed or sources that are reconstructed or modified on or after a specified date. The EG are similar to the NSPS, except that they apply to existing sources—that is, sources whose construction begins on or before the date the EG are proposed, or sources that are reconstructed or modified before a specified date. Unlike NSPS, the EG are not enforceable until EPA approves a state plan or adopts a federal plan for implementing and enforcing them, and the state or federal plan becomes effective.

The CISWI Rule established emission limitations for new and existing CISWI units for the following pollutants (or surrogates): cadmium, carbon monoxide, dioxins/furans, hydrogen chloride, lead, mercury, oxides of nitrogen (NO_x), particulate matter (PM), sulfur dioxide (SO₂), and opacity. In addition, the rule established certain monitoring and operator training and certification requirements. See 65 FR 75338 for a more detailed discussion of the CISWI Rule.

The CISWI Rule was subject to judicial challenge in *Sierra Club v. EPA* (No. 01–1048) (D.C. Cir.) and a separate petition for reconsideration of the final rule. The petition argued that the final rule was procedurally defective because EPA had failed to provide adequate notice and an opportunity to comment on the definitions adopted in the final rule. Also, after promulgation of the CISWI Rule, the court issued its decision in *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855 (D.C. Cir. 2001) (“Cement Kiln”). In this decision, the court rejected certain common elements of EPA’s MACT methodology. As a result, EPA requested a voluntary remand of the CISWI Rule, in order to address concerns related to the issues that were raised by the court in *Cement Kiln*. The court granted the voluntary remand and remanded, without vacatur, the CISWI Rule back to EPA, thereby terminating the case (see Order dated September 6, 2001). Because the CISWI Rule was not vacated, its requirements remain in effect. See *Sierra Club v. EPA*, 374 F. Supp.2d 30, 32–33 (D.D.C. 2005). In addition to taking a voluntary remand of the CISWI Rule, EPA also granted an administrative petition for reconsideration on February 17, 2004 related to the definitions of “solid waste,” “commercial or industrial

¹ CAA section 129 refers to the Solid Waste Disposal Act (SWDA). However, this act, as amended is commonly referred to as RCRA. Thus, the term, “RCRA” is used in place of SWDA in this Notice.

waste” and “commercial and industrial solid waste incineration unit” in the CISWI Rule.

EPA responded to the petition for reconsideration on September 22, 2005, by re-promulgating the definitions of “solid waste,” “commercial or industrial solid waste incineration unit” and “commercial or industrial waste” (the CISWI Definitions Rule). See 70 FR 55568. In the CISWI Definitions Rule, EPA distinguished solid waste incinerators from boilers/furnaces based on the function of the units. Solid waste incinerators included units designed and operated to discard materials through high temperature combustion, but excluded units designed and operated to recover energy for a useful purpose.

The CISWI Definitions Rule was the subject of judicial challenge in *NRDC v. EPA* (489 F.3d 1250 (D.C. Cir. 2007)) where the court vacated the definitions of “commercial or industrial solid waste incineration unit” and “commercial or industrial waste.” The court observed that, although the functional distinction EPA drew between boilers/furnaces and incinerators “may well be reasonable,” the statute unambiguously requires any unit that combusts “any solid waste material at all”—regardless of whether the material is being burned as a fuel—to be regulated as a “solid waste incineration unit.” *Id.* at 1260. The court also vacated and remanded the Boilers Rule, concluding that EPA erred by excluding units that combust solid waste for the purposes of energy recovery from the CISWI Rule and including such units in the Boilers Rule.

Therefore, the critical issue in responding to the court’s decision is for EPA to establish, under RCRA, which non-hazardous secondary materials² constitute “solid waste.” This is necessary because, under the court’s decision, any unit combusting any “solid waste” at all must be regulated as a “solid waste incineration unit,” regardless of the function of the combustion device. If a non-hazardous material is not a “solid waste” under RCRA and such material is burned for fuel value or used as an ingredient in a manufacturing process, then under the court’s decision, the combustion unit would properly be regulated pursuant to CAA section 112. Alternatively, if such

material is a “solid waste” under RCRA and is burned for fuel value or used as an ingredient in a manufacturing process and such ingredient is combusted, then the unit must be regulated under CAA section 129.

B. Sections 112 and 129 of the CAA

CAA section 112 requires EPA to promulgate regulations to control emissions of 187³ hazardous air pollutants (HAP) from major sources⁴ in each source category listed by EPA under section 112(c). The statute requires the regulations to reflect the maximum degree of reduction in emissions of HAP that is achievable taking into consideration the cost of achieving the emission reduction, any non-air quality health and environmental impacts, and energy requirements. As noted previously, this level of control is commonly referred to as MACT.

For new sources, MACT standards cannot be less stringent than the emission control achieved in practice by the best-controlled similar source (see CAA section 112(d)(3)). The MACT standards for existing sources cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources for categories and subcategories with 30 or more sources, or the best-performing 5 sources for categories or subcategories with fewer than 30 sources (*Id.*). This level of control is usually referred to as the MACT “floor,” the term used in the Legislative History.

Like the CAA section 112 standards, the CAA section 129 standards are based on a MACT floor. Also, as with the section 112 standards, above-the-floor standards may be established where EPA determines it is “achievable” taking into account costs and other factors. Although CAA section 129 “establishes emission requirements virtually identical to section [112’s],” *Nat’l Lime Ass’n v. EPA*, 233 F.3d at 631, the two sections differ in three primary respects. First, CAA section 112 requires that MACT standards be established for major sources of HAP emissions, but provides discretionary authority to establish MACT standards for area sources of HAP emissions.⁵ On

the other hand, the CAA section 129 MACT standards apply across the board to all solid waste incineration units in a given category regardless of size. Second, CAA section 129 requires that emission standards be set for specific HAP and certain pollutants that are not classified as CAA section 112 HAP.⁶ Specifically, CAA section 129 requires numeric emission limitations for the following nine pollutants: Cadmium, carbon monoxide, dioxins/furans, hydrogen chloride, lead, mercury, NO_x, particulate matter (total and fine), opacity (as appropriate), and SO₂.⁷ The CAA section 129 pollutants listed above represent the minimum that must be regulated; EPA has the discretion to establish standards for other pollutants as well. Third, CAA section 129 includes requirements for operator training, pre-construction site assessments, and monitoring that are not included in CAA section 112. See CAA section 129(a)(3), (c) and (d). Rather, CAA section 112’s implicit authority and CAA sections 113 and 114’s explicit authority is relied upon to include provisions as necessary to assure compliance with and enforcement of the emission limitations. It is important to note that CAA section 129(h)(2) specifies that no solid waste incineration unit subject to the performance standards under CAA sections 111 and 129 shall be subject to the standards under CAA section 112(d).

III. Beneficial Use of Secondary Materials

A. Introduction

EPA supports exploring regulatory alternatives that achieve the following goals: Maximizing the usefulness of secondary materials in production, reducing or eliminating waste, conserving energy, and reducing harmful air emissions. Such alternatives should ensure protection of human health and the environment, and one alternative would be an integrated management approach that includes emissions and source reduction and

Administrator finds that the sources “presen[t] a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation under this section.” Section 112(c)(3). Certain categories of area sources must be regulated in accordance with section 112(c)(3) and (k)(3)(B).

⁶ This is in reference to the initial list of 190 HAPs provided by Congress.

⁷ Of these nine pollutants, cadmium, dioxins/furans, hydrogen chloride, lead, and mercury are also regulated HAP pursuant to CAA section 112, and particulate matter and carbon monoxide are commonly used as surrogate emission standards to control specific CAA section 112 HAP (e.g., CAA section 112 HAP metal and organic emissions).

³ EPA has delisted 3 of the 190 HAP initially listed in section 112(b)(1): Methyl ethyl ketone, glycol ethers, and caprolactam.

⁴ A “major source” is any stationary source that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP. CAA section 112(a)(1).

⁵ An “area source” is any stationary source of HAP that is not a major source. CAA section 112(a)(2). Area sources may be regulated under CAA section 112(d)(2) standards if the

² A secondary material is any material that is not the primary product of a manufacturing or commercial process, and can include post-consumer material, post-industrial material, and scrap. Many types of secondary materials have Btu or material value, and can be reclaimed or reused in industrial processes. For purposes of this notice, the term secondary materials include only non-hazardous secondary materials.

recycling, as well as energy capture and resource recovery from secondary materials. For example, within the context of RCRA,⁸ the Agency seeks to achieve these goals through promotion of the use or reuse of various secondary materials, provided such reuse activity is protective of human health and the environment. EPA seeks to accomplish this in conjunction with our state partners through research, analysis, communication, and outreach.

To help put this discussion into context, the Agency notes that non-hazardous secondary materials are widely used today as fuels or ingredients in industrial processes. We expect this trend will continue with higher prices for energy and materials and advancing technology in secondary material use.

The nature of what constitutes a legitimate fuel or ingredient reflects the availability of natural resources and technology development. The use of materials from a variety of non-traditional sources, including the use of energy-containing secondary materials, may have a significant role to play in our resource conservation efforts.

The use of non-hazardous secondary materials as alternative fuels and ingredients in manufacturing processes using combustion has a long history, and is increasingly becoming an accepted characteristic of the modern industrial economy.⁹ Under conditions in the past, many secondary materials may have been managed as wastes—that is, they were discarded. However, if the cost of fossil fuel increases and technology advances, such materials become comparatively more valuable as an energy source, ingredient, or both. Furthermore, the use of some of these materials is likely to contribute to certain emission reductions and may increase other emissions.¹⁰

The reuse of secondary materials may result in other benefits. First, the use of secondary materials could result in

reduction of imported fuel. Second, using secondary materials for fuel or ingredient value has an additional benefit of reducing the environmental impacts caused by the disposal of such materials, if such disposal has environmental impacts. For example, use of tires as a fuel source means that those tires are no longer accumulated in huge piles where there are known incidents of them catching fire and serving as breeding grounds for disease carrying mosquitoes.^{11 12}

The remainder of this section first presents an overview of the secondary materials and their contribution to improved economic efficiency. Then, we briefly summarize selected materials management programs and successes. Finally, we discuss known use patterns for selected secondary materials and briefly summarize some economic and environmental benefits derived from the use of such materials.

B. Overview of Secondary Materials and Their Contribution to Economic Efficiency

There exists a wide and diverse range of secondary materials used as fuels and/or ingredients, or otherwise beneficially used. Although sometimes referred to as wastes, these secondary materials may, in most cases, be more appropriately defined as “by-products,”¹³ reflecting their inherent resource recovery value in the generation/production of heat, energy, and/or marketable products. This inherent value exists with or without processing, depending upon the material. These secondary materials commonly include, but are not limited to, the following: scrap tires; scrap plastics; the biomass group (pulp and paper residuals, forest derived biomass,¹⁴ agricultural residuals, food scraps, animal manure, gaseous fuels); the construction and demolition material group (building related, disaster debris, and land clearing debris); spent solvents; coal refuse; waste water treatment sludge; used oil; blast furnace slag; cement kiln dust

(CKD); coal combustion products (e.g., fly ash, bottom, ash, boiler slag); foundry sand; silica fume; and secondary glass material. These secondary materials can provide significant and widespread environmental and economic benefits when legitimately used/reused as an effective substitute for, or supplement to, primary materials.

As certain primary materials become costly, the use of secondary materials is likely to become more economical. Managers of manufacturing or energy-production units that use secondary materials as a substitute for primary fuels or ingredients are obviously doing so for their own interests, including short and/or long-term competitive advantage. In general, industry will use secondary materials so long as the final price to the user is equivalent or less than the price for comparable primary material(s), and the product(s) derived from these materials is of equal (or better) quality. Provided industry is able to continue to safely use secondary materials, economic efficiency may be improved. While the issue raised in this ANPRM is whether specific secondary materials are properly considered legitimate products, or RCRA solid wastes, EPA notes that the regulatory status of the fuel or ingredient may, as mentioned above, potentially affect choices made by industrial concerns in selecting raw materials.

C. Materials Management Programs and Successes

EPA, like environmental agencies in other countries, is exploring approaches to waste management that employs the concepts of life cycle assessment¹⁵ and full cost accounting.¹⁶ The life cycle approach has been advanced in the EU where, for the past several years, the EU has been focused on developing a strategy designed to minimize and recycle secondary materials,¹⁷ while recognizing the importance of full life cycle analysis within a comprehensive materials management program. Japan has gone even further, passing ambitious laws and establishing an

⁸ RCRA Section 6901(c)—Materials: The Congress finds with respect to materials, that—(1) Millions of tons of recoverable material which could be used are needlessly buried each year; (2) methods are available to separate usable materials from solid waste; and (3) the recovery and conservation of such materials can reduce the dependence of the United States on foreign resources and reduce the deficit in its balance of payments.

⁹ For example, use of tire-derived fuel in the cement industry began in Japan and Germany in the 1970s. See docket item titled “Scrap Tire Markets in the United States,” RMA, November 2006. Also, the market for woody biomass is strong in Europe, where this material sells for \$100 to \$125 per ton. See docket item titled “Biocycle, Advancing Composting, Organics Recycling and Renewable Energy,” July 2008.

¹⁰ See the Materials Characterization Papers in the docket established for this action for examples of emission comparisons.

¹¹ Although this notice highlights the benefits of using secondary materials as fuels, EPA recognizes that there may be other uses of secondary materials that in some cases are preferable from an energy perspective. For example, re-refining used oil is reported to save more energy content of the used oil than burning for energy recovery.

¹² See docket entry titled “Scrap Tire Cleanup Guidebook, January 2006,” for more discussion on hazards associated with tire piles.

¹³ For purposes of this action, we define by-product as a secondary or incidental material derived from the primary use or production process that has value in the marketplace, or value to the user.

¹⁴ More commonly referred to as scrap wood materials.

¹⁵ Note: The terms, “life cycle analysis” and “life cycle assessment” are commonly used interchangeably. Life cycle assessment is a system-wide analytical technique for assessing the environmental (and sometimes economic) effects of a product, process, or activity across all life stages.

¹⁶ Full cost accounting is an accounting system that incorporates economic, environmental, health, and social costs of a product, action, or decision.

¹⁷ For example, The Closed Substance Cycle and Waste Management Act of 1994 (Germany), the German Auto Recycling Law, Directive 2006/66/EC of the European Parliament (EU battery recycling law).

effective initiative¹⁸ focused on creating a “closed loop” economy.

EPA’s materials management approach is focused on the three R’s: Reduce, reuse, and recycle.¹⁹ This approach helps ensure more efficient resource and material use through the integration of both environmental and economic components in the management of materials. In 2002, EPA initiated the Resource Conservation Challenge (RCC). This program was designed to help implement the Agency’s approach to materials management. The RCC Program is currently focused on four specific material groups: Municipal solid waste; green initiatives, such as electronics; industrial materials; and priority and toxic chemicals. The Agency also has materials management programs focused specifically on used oil and scrap tires.²⁰ Other more broadly focused EPA programs include the Office of Solid Waste’s (OSW’s) Product Stewardship Program and the Comprehensive Procurement Guidelines. In addition, several states have also established life cycle approaches to materials management (e.g., California, Minnesota, Washington, and Vermont).

The Agency has an interest in understanding the environmental and economic tradeoffs associated with life cycle implications of our materials management programs. For example, we have conducted preliminary life-cycle analyses of beneficial impacts associated with recycling of foundry sand and selected coal combustion products.²¹ It is also one of our mandates under RCRA Subtitle F—Federal Responsibilities, which states the “Administrator shall provide information on the technical and economic aspects of developing integrated resource conservation or recovery systems * * *” (Sec. 6003). For the examples cited above, the Agency used a rigorous analytical approach to evaluate the environmental

and economic benefits associated with the management of those materials. This rigorous analytical approach to the development of materials management programs helps to ensure that we are not promoting economically or environmentally inefficient programs. Where we have evaluated the benefits of secondary materials management programs, such as the RCC’s Program as described above for uses of foundry sand and selected coal combustion products, our analyses have shown those programs provide benefits.

We believe that it is critical to interpret which secondary materials are not “solid wastes” pursuant to RCRA to ensure the continued legitimate use of secondary materials in combustion processes. This, in turn, will maintain the continued environmental and economic benefits from these programs.

D. Secondary Materials Use and Benefits

This part builds on the discussion in part “B” of this section and provides greater detail on some of the non-hazardous secondary materials that are commonly used by the industrial community. We summarize key information that is available on the known generation, use, and benefits of these secondary materials. The purpose of this part is to describe the Agency’s understanding regarding the wide-scale acceptance, use, and value of these secondary materials in U.S. industrial markets. More detailed information on a wide array of secondary materials potentially affected by this action is presented in the Materials Characterization Papers, which can be found in the Docket established for today’s action.

The Materials Characterization Papers outline publicly and readily available information concerning material characteristics relevant to this ANPRM. Specifically, for each material group, the papers endeavor to: (a) Provide a clear definition of the material; (b) identify annual quantities generated and used; (c) outline current combustion and non-combustion uses, along with current quantities landfilled or otherwise stored; (d) discuss management and combustion processes utilized; and (e) summarize potential environmental and economic impacts from the use of each material. The available information across these components of each paper and the individual materials is often limited or uncertain. Thus, these papers represent our initial effort to gather and present relevant data. The Agency seeks comment on additional data sources that may enhance its understanding and knowledge of these materials.

Non-hazardous secondary materials are widely used as fuels and/or ingredients in virtually all types of boilers (e.g., industrial, commercial, institutional), cement kilns, lightweight aggregate kilns (LWAKs), and other industrial furnaces (e.g., glass furnaces). These facilities burn or otherwise use in the production process hundreds of millions of tons of secondary materials each year. The total number of facilities using secondary materials each year as a substitute for primary fuels and/or ingredients is unknown, but our best estimate indicates that approximately 200,000 units use secondary materials as a substitute for primary fuels and/or ingredients.²²

The manner in which non-hazardous secondary materials are processed, the nature of the materials, and the ways in which they are used or recycled generally establishes whether such materials are wastes or “by-products.” Based on our research for the Materials Characterization Papers, we have identified eight non-hazardous secondary material fuels or fuel groups and six non-hazardous ingredients, or ingredient groups. The eight fuel source materials are: The biomass group (pulp and paper residuals, forest derived biomass, agricultural residues, food scraps, animal manure, gaseous fuels); construction and demolition materials (building related, disaster debris, and land clearing debris); scrap tires; scrap plastics; spent solvents; coal refuse; waste water treatment sludge, and used oil. The six secondary material ingredients are: Blast furnace slag; CKD; coal combustion product group (fly ash, bottom ash, and boiler slag); foundry sand; silica fume; and secondary glass material.

Based on publicly available information, we believe that these materials account for the vast majority of all non-hazardous secondary materials used as fuels and/or ingredients in the U.S. However, the Agency solicits comment on whether there are other non-hazardous secondary materials that are also used as a fuel or ingredient that we have not identified, either in this notice or in the Materials Characterization Papers. If so, the Agency requests that commenters provide information on such materials, including the composition or characteristics of such materials, how much of the secondary material is produced and utilized, how it is utilized—that is, is it a fuel or an

¹⁸ The Japanese law Promoting the Utilization of Recyclable Resources, 1991, the Japanese Recycling Law, 2001 (the world’s first “take back” law), and The Ecofactory initiative (Ministry of International Trade and Industry).

¹⁹ See: <http://www.epa.gov/epawaste/rcc/basic.htm>.

²⁰ See: <http://www.epa.gov/waste/conserves/materials/usedoil/index.htm>, and, <http://www.epa.gov/waste/conserves/materials/tires/index.htm>.

²¹ See docket items titled “Waste and Materials-Flow Benchmark Sector Report: Beneficial Use of Secondary Materials—Coal Combustion Products, Final Report,” USEPA, February 12, 2008 and “Waste and Materials-Flow Benchmark Sector Report: Beneficial Use of Secondary Materials—Foundry Sand, Final Report,” USEPA, February 12, 2008.

²² Identification of Non-Hazardous Materials That Are Solid Waste. EPA Exhibit 1: Preliminary Estimate of Total Nonhazardous Secondary Materials Used Annually in Boilers and Kilns. Sept. 24, 2008.

ingredient, and how it is generally handled. Detailed information will be the most useful as we move forward in the rulemaking effort.

The annual use patterns, quantities, and benefits associated with some of these secondary materials are well established, while less is known about other secondary materials. Presented below are brief summaries of the documented usage, trends in usage, and benefits associated with some of these widely used secondary materials. As mentioned above, the Materials Characterization Papers, available in the docket established for today's action, present more detailed information on the quantities and use patterns, characteristics, composition, management and benefits associated with all eight secondary fuel materials/groups and the six secondary ingredient materials/groups we have identified.

Biomass²³—When used as a secondary material fuel, biomass consists primarily of pulp and paper mill residuals, forest derived biomass, agricultural residuals, food scraps, animal manure, and gaseous fuels. Sectors that generate and/or use these valuable biomass commodities include: Crop production; support activities for crop production; food manufacturing; beverage and tobacco product manufacturing; logging; pulp, paper, and paperboard mills; sawmills and wood preservation; veneer, plywood, and engineered wood product manufacturing; cattle ranching and farming; hog and pig farming; poultry and egg production; sheep and goat farming; horses and other equine production; and, sewage treatment facilities.

Timber harvesting and the manufacture of lumber generate large amounts of forest-derived biomass used as secondary material fuels. These woody materials may originate directly from the forest as logging residues (e.g., tree limbs, tops, needles, leaves), or from timber processing mills (e.g., clean and unadulterated bark, sawdust, trim, screenings, tree harvesting residuals). Logging and other forest harvesting removal residues are estimated to range from 62 million tons per year (tpy) to 103 million tpy, with an estimated 42 to 93 million tpy available for recovery and beneficial use. Total primary mill²⁴ residue production is estimated to range from 87 to 91 million tpy. Experts predict that by 2050, logging and other

forest harvesting removal residues will increase by 23 million tpy and availability of secondary mill residues (i.e., residues such as board, trim and breakage from the manufacture of reconstituted wood/panel products) will increase by 16 million tpy.

Available information indicates that logging residues, although a good potential source for secondary material fuel, are not currently collected for use as a fuel on any large scale. Primary mill residues, however, are highly valuable as feedstocks in combustion, as well as for non-combustion purposes.²⁵ Approximately 42 percent of all primary mill residues are used as a fuel, including 76 percent of bark residues, 12 percent of coarse residues, and 56 percent of fine residues. These materials are burned in a variety of boilers, including Dutch ovens, fuel cell ovens, spreader stokers, suspension-fired boilers, and fluidized bed combustion boilers. Forest-derived materials may also be co-fired with other fuels, primarily solid fuels such as coal. Logging and primary milling residues may be chipped or sorted before being used, but otherwise generally undergo minimal processing. The use of forest-derived materials has been found to result in generally higher PM emissions than natural gas or distillate oil, but lower PM emissions than coal or residual oil systems. Estimated NO_x emissions associated with the use of wood are similar to those associated with distillate and lower than the NO_x emissions for other conventional fuels, while wood combustion results in lower SO₂ emissions than most conventional fuels. Finally, the use of forest-derived materials results in reduced fuel costs to the user and may provide environmental benefits associated with avoided virgin material²⁶ extraction and, in some cases, avoided transportation.

The forest products industry generates large quantities of secondary material biomass fuels in the form of pulp and paper residues, including sludges and black liquor.²⁷ However, black liquors that are reclaimed in a pulping liquor recovery furnace and then reused in the pulping process are excluded from the definition of solid waste under Subtitle C of RCRA, unless speculatively accumulated, as defined in 261.1(c), or

reclaimed in another manner. Pulp and paper mills produce the dry biomass equivalent of between 4.2 and 5.8 million tons of wastewater treatment sludges. In 2002, approximately 22 percent of all pulp and paper mill sludges were used in hog fuel boilers as a supplementary or stand-alone fuel. An undetermined amount was used as a cement kiln feedstock and as a fuel pellet ingredient. Anaerobic sludge production also generates methane. Sludges typically undergo mechanical dewatering before being combusted. The use of mill sludges in onsite boilers results in reduced fuel costs for the facility, and may provide environmental benefits associated with avoided virgin material extraction and transportation.

Agricultural residuals include crop residues remaining in the fields after harvest (primary residues) and processing residues generated from the harvested portions of crops during food, feed, and fiber production (secondary residues). Current annual production of agricultural residues from major crops is estimated to be around 500 million dry tpy. These primary biomass crops include barley, canola, corn, cotton, dry beans, flax, oats, peanuts, peas, potatoes, rice, rye, safflower, sorghum, soybeans, sugarcane, sunflowers, and wheat. Anywhere from 113 million tpy to 173 million tpy is estimated to be available for removal from the fields in a sustainable manner (i.e., while maintaining cropland fertility and quality). However, the total quantity of agricultural residues actually used for fuel on an annual basis is difficult to determine from the available literature. Total primary agricultural residue production fluctuates with the amount of U.S. land in crop production and the relative proportion of crops on this land. In 2007, we estimate that approximately 6.0 million tons of agricultural residues were burned, 92 percent of which [on a British thermal unit (Btu) basis] provided useful thermal output. The remaining 8 percent was used to produce electricity. Around 71 percent of total agricultural residues burned (Btu basis) were secondary residues used in the food processing industry, mostly sugarcane bagasse at sugar mills. The remaining 29 percent was used in the Agriculture, Forestry, and Mining, and the Paper and Allied Products industries. Corn stover and other agricultural residues can be used as a heat and power source for the production of corn and cellulosic ethanol. Agricultural residues are generally burned as fuel in fuel cells, horseshoe boilers, and spreader stoker boilers. Aside from occasionally drying,

²⁵ Primary mill residues tend to be clean, uniform, concentrated, and with a low-moisture content. As a result, these materials generally require little processing.

²⁶ The term "Virgin material," as used in this Notice means resources extracted from nature in their raw form, such as timber, metal ore, coal, petroleum, etc.

²⁷ See 40 CFR 261.4(a)(6).

²³ Source: Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of Non-Hazardous Materials That Are Solid Waste—Biomass.

²⁴ Lumber and veneer mills.

agricultural residues do not generally require processing prior to being utilized as a fuel. The use of agricultural residues as a substitute for coal in an existing power plant reduces SO₂, NO_x, and other emissions and eliminates the environmental impacts associated with the extraction and processing of the traditional fuels.

Food scraps are generated at all stages of the food production system, including farming, storage, processing, wholesaling, retail, and consumption. Food scraps, broadly defined, include both the portion of harvested crops and livestock that does not enter the retail market and the portion of food discarded by retailers and consumers. This ANPRM is concerned only with industrial food scraps; food scraps generated by retailers and consumers are not considered because they enter the waste stream as municipal solid waste. The total quantity of industrial food scraps produced on an annual basis is not readily accessible from publically available information. Industrial food scraps are known to be burned in lodging and restaurant boilers. However, the annual quantities burned and the distribution of this use is unknown. The use of food scraps with meaningful fuel value in lodging and restaurant boilers eliminates the environmental impacts associated with the extraction and processing of the traditional fuels.

Animal manure is the excrement of livestock reared in agricultural operations. Animal manure may also include straw, sawdust, and other residues used as animal bedding. Gaseous fuels may be derived from landfills (landfill gas) or from animal manure and solid biomass (biogas), such as crop silage. Biogas is generated via anaerobic digestion, a multi-stage process whereby bacteria convert carbohydrates, fats, and proteins to methane. Domestic livestock production generates over a billion tons of manure annually, which if used to produce biogas would yield approximately 19.4 million tons of methane. Anaerobic digestion of current manure production managed in ponds, anaerobic lagoons, and holding tanks could yield a maximum of about 2.4 million tpy of methane. Current production, however, is about 0.07 million tons from 111 operating digesters.

We estimate that about 35 million dry tons of current manure production could be used for bioenergy purposes. Livestock production has become increasingly concentrated in recent years, facilitating the collection of manure for bioenergy purposes. As bioenergy conversion technologies

improve, the opportunity for utilizing animal manure for bioenergy production may likely increase. Biogas produced on dairy farms is typically used to heat water for purposes of cleaning and sanitizing milking pipelines and equipment in dairy operations. Biogas generated on farms is typically burned on-site directly in boilers and, to a lesser extent, is burned in space heating. Biogas benefits include displacement of fossil fuels, primarily natural gas. Furthermore, the use of biogas as a replacement for natural gas avoids the emissions associated with the extraction and processing of natural gas.

*Scrap tires*²⁸—Scrap tires are used tires that are recycled when they can no longer be used as tires. This may occur because of normal tread wear, punctures, destruction in accidents, or any number of other reasons. Scrap tires are generated from the replacement of tires on passenger and commercial vehicles. Consumers and industry in the U.S. generated 299.6 million tires in 2005; this represents approximately 4.9 million tons of tires, assuming an average of 33 pounds per tire. Approximately 52 percent of the total number of scrap tires generated in 2005 went for tire-derived fuel (TDF).²⁹ Although energy recovery is the most common use of scrap tires, there are many non-fuel uses for scrap tires, including: Civil engineering (i.e., construction of landfills and roads); cut/punched/stamped into other products (i.e., floor mats); and, rubber modified asphalt. While some facilities are capable of burning whole tires, a large percentage of tires are sent to processors where they are shredded or chipped prior to being sent to plants for use as TDF. Facilities that burn whole tires often charge a tipping fee for acceptance of these tires, while chipped tires must be purchased. TDF is used in a variety of units, including boilers and industrial furnaces, such as kilns. It can be used to supplement and/or replace a wide range of fuels including coal, coke, fuel oil, natural gas, and wood. The use of tires for fuel has increased from 24.5 million tires in 1990 to 155.1 million tires in 2005. During this same period, the number of tires in stockpiles declined by nearly 82 percent, going from approximately one billion tires to just under 200 million, a significant environmental accomplishment. The majority of tires that have been removed from these piles have been used in

²⁸ Source: Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of Non-Hazardous Materials That Are Solid Waste—Scrap Tires.

²⁹ TDF has a heating value of around 13,000 to 16,000 Btu/lb.

industrial boilers and kilns for energy recovery. This trend may increase if the cost of conventional fossil fuels increases.

Emissions test data compiled by EPA in 1997 suggest that substituting scrap tires for coal in electric utility boilers may lead to reductions in NO_x and particulate matter emissions,³⁰ but show no clear pattern for SO_x and zinc emissions.³¹ Studies indicate that there is an increase in zinc emissions when TDF is used at industrial boilers and pulp and paper mills, while zinc emission data are inconclusive for cement kilns and utility boilers. Finally, as referenced above, the use of TDF as a replacement for traditional primary fuels eliminates the environmental impacts associated with the extraction and processing of the traditional fuels.

*Used Oil*³²—Used oil is defined as petroleum-based or synthetic oil that has been used and has been contaminated from use (see 40 CFR 279.1 for the specific definition). To meet EPA's regulatory definition, contamination includes residues and contaminants generated from the handling, storing, use, and processing of oil.³³ Physical contaminants from use include metal shavings, high water content, or dirt, while chemical contaminants from use include solvents, halogens, or lead. To meet EPA's regulatory definition, used oil must have been refined from crude oil or made from synthetic materials; animal and vegetable oils are excluded from EPA's regulatory definition of used oil. Generators of used oil include businesses that handle oil through commercial or industrial operations or from the maintenance of vehicles and equipment. The oil may have been used as a lubricant, hydraulic fluid, heat transfer fluid, buoyant, and for other similar purposes.

³⁰ United States Environmental Protection Agency (EPA). 1997. "Air Emissions from Scrap Tire Combustion".

³¹ See also the Nebraska Department of Environmental Quality, Applicability Determination for Combusting Tire Derived Fuel in Humboldt Wedag Kiln (Kiln #2), indicates that emissions of SO₂, NO_x, and CO decreased while TDF was used. (see: <http://www.deq.state.ne.us/Press.nsf/pages/AGFactsheet1>)

³² Source: Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of Non-Hazardous Materials That Are Solid Waste—Used Oil.

³³ Used oil processing is defined as a chemical or physical operation designed to produce from used oil, or to make used oil more amenable for production of fuel oils, lubricants, or other used oil-derived products. Processing includes, but is not limited to: blending used oil with primary petroleum products, blending used oils to meet the fuel specification, filtration, simple distillation, chemical or physical separation and re-refining.

Recent estimates indicate that approximately 1.35 billion gallons of used oil are collected each year. Depending upon the year, our estimates indicate that as much as 90 percent of all collected used oil is burned for energy recovery. Both on-specification and off-specification³⁴ used oil may be used as a source of fuel in combustion units. However, off-specification used oil may only be burned in the following types of boilers: industrial boilers located at facilities that are engaged in a manufacturing process where substances are transformed into new products; utility boilers used to produce electric power, steam, heated or cooled air or other gases or fluids for sale; used oil-fired space heaters provided that the burner meets the provisions of 40 CFR 279.23; and hazardous waste incinerators subject to regulation under 40 CFR subpart O of parts 264 or 265. National information on the distribution between on-specification and off-specification used oil used as a fuel is not readily available. However, asphalt plants appear to be the largest users of used oil, followed by space heaters, and industrial boilers. We estimate that approximately 73 percent of all used oil generated and used each year is on-specification.

The long-term trend in used oil generation is undetermined. However, during the 1997–2005 time period, the recycling rate for used oil generated by service stations increased from 66 percent to almost 100 percent.

The principal environmental benefits of burning used oil for energy recovery are associated with upstream production offsets and include substantial reductions of NO_x and carbon monoxide (CO) emissions. In terms of combustion-specific emissions, use of used oil results in notably lower NO_x emissions, in particular when compared to residual fuel oil. However, PM and lead emissions may be higher than for primary fuel oil, depending upon the extent of processing.

*Coal Fly Ash*³⁵—Exhaust gases leaving the combustion chamber of a

power plant entrain particles during the coal combustion process. Fly ash is the finest of coal ash particles. To prevent this fly ash from entering the atmosphere, power plants use various collection devices to remove it from the gases that are leaving the stack. The coal-fired power industry is the largest generator of coal fly ash in the U.S. and other industries that use coal as a fuel, such as commercial boilers and mineral and grain processors, also produce coal fly ash. In 2006, the coal-fueled electric power industry generated approximately 72.4 million tons of fly ash. This figure was estimated at 70.8 million tons for 2004 and 71.7 million tons for 2007.³⁶ Electricity demand is projected to increase in coming years.³⁷ Because coal is expected to continue to be an important fuel source, it is likely that the quantity of coal fly ash generated will also remain significant.

Coal fly ash can be added to the raw material feed in clinker manufacturing to contribute specific required elements, such as silica, alumina, and calcium, in the final cement composition. Coal fly ash with relatively high unburned carbon content can also be re-burned in cement kilns for energy recovery at the same time as it provides ingredient value. The use of coal fly ash as an ingredient in cement kilns does not require processing. However, levels of key metals in coal fly ash must be carefully calibrated with other ingredients to ensure that the final cement product has the correct mineral and metal content. In clinker manufacture, coal fly ash partially offsets the need for raw materials, such as silica, iron, and alumina sources. Thus, using coal fly ash in the cement kiln can reduce the unit consumption of raw feed stock materials, which results in reduced emissions of certain pollutants.³⁸ Furthermore, when coal fly ash with relatively high unburned carbon content is introduced to the cement kiln during clinker manufacture,

the primary fuel supply may be reduced to accommodate the additional energy provided by the carbon in the fly ash.

*Cement Kiln Dust (CKD)*³⁹—Generated by the cement manufacturing industry, CKD is a fine-grained, solid, highly alkaline low organic content material removed from the cement kiln exhaust gas by scrubbers. Much of the material comprising CKD is incompletely reacted raw material, including a raw mix at various stages of burning, and particles of clinker. There is an estimated 13 to 17 million short tons of CKD generated per year in the U.S. CKD can be directly reused in a closed-loop process back into the cement kiln as an ingredient for clinker manufacture. The cement industry is estimated to recycle more than 75 percent of its CKD each year. Significant increases in U.S. clinker capacity are expected over the 2008 to 2012 period resulting in an anticipated increase in CKD production and usage. In clinker manufacture, CKD partially offsets the need for raw material feed, such as limestone and natural constituents (rock), thus avoiding the energy usage and emissions related to their extraction and processing.

*Coal Refuse*⁴⁰—Coal refuse refers to any by-product of coal mining or coal cleaning operations. Coal refuse is generally defined by a minimum ash content combined with a maximum heating value, measured on a dry basis. Coal refuse consists primarily of non-combustible rock with attached coal that could not be effectively separated in the era in which it was mined. Coal refuse includes mining rejects and recovered landfill ash. Coal mine rejects are generated by bituminous coal and lignite surface mining, bituminous coal underground mining, and anthracite mining. Recovered landfill ash is generated by fossil fuel electric power generation facilities. Specific data on the quantity of mining rejects generated is not available. However, we estimate that up to 1,145 million tons of coal refuse may have been generated⁴¹ in 2007. Generation of mining rejects, as well as the availability of recoverable

³⁴ The Agency makes a distinction between on-specification and off-specification used oil. Only certain contaminants in used oil pose a significant threat to human health or the environment. As a result, EPA has established maximum concentration limits for these constituents of concern. These limits are set such that the emissions resulting from the burning of used oil containing these contaminants, at or below established “on-spec” limits, will pose no more threat to human health or the environment than the emissions resulting from the burning of virgin oil or diesel. See 68 FR 44662 (July 30, 2003). Also see Section V.A.4. for more discussion of used oil.

³⁵ *Source* (unless otherwise noted): Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of

Non-Hazardous Materials That Are Solid Waste—Coal Combustion Products—Includes Coal Fly Ash, Bottom Ash, and Boiler Slag.

³⁶ ACAA. 2004 and 2007 Coal Combustion Product (CCP) Production and Use Survey Results (Revised for 2007).

³⁷ See United States Department of Energy, Energy Information Administration (EIA). 2008, “Annual Energy Outlook 2008 with Projections to 2030,” Publication DOE/EIA-0383 (2008), June 2008.

³⁸ For more detailed information on the benefits of using coal fly ash and other recovered mineral components in manufacturing processes, please see: “Study on Increasing the Usage of Recovered Mineral Components in Federally Funded Projects Involving Procurement of Cement or Concrete to Address the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users.” June 23, 2008. (EPA530-R-08-007)

³⁹ *Source* (unless otherwise noted): Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of Non-Hazardous Materials That Are Solid Waste—Cement Kiln Dust (CKD).

⁴⁰ *Source* (unless otherwise noted): Materials Characterization Paper in Support of the Advanced Notice of Proposed Rulemaking: Identification of Non-Hazardous Materials That Are Solid Waste—Coal Refuse.

⁴¹ The term “generated” in this context refers to the quantity of coal mining rejects produced from the total quantity of U.S. coal mined in 2007. (Please see the coal refuse Materials Characterization Paper for a more detailed discussion.)

landfill ash, correlates with the production and use of coal. Coal production is projected to increase in the coming decades in response to increased demand for electricity. Increasing coal use for electricity generation at existing plants and projected construction of new coal-fired plants is estimated to lead to coal production increases that average 1.1 percent per year from 2005 to 2015, with 1.8 percent annual growth projected over the 2015 to 2030 period. Based on our review of publicly available information, circulating fluidized bed (CFB) combustion units and pulverized coal power plants are currently the units that use coal refuse.

CFB is an integrated technology for reducing SO₂ and NO_x emissions during the combustion of coal. In addition to reduced SO₂ and NO_x emissions, use of coal refuse as a replacement for traditional primary fuels eliminates the environmental impacts associated with the extraction and processing of traditional fuels, and reduces the environmental impacts that may be associated with the piles of coal refuse (e.g., potential fire hazards and sources of surface and groundwater pollution).

The Agency seeks comment, with supporting data, on the secondary materials information provided in this ANPRM and in the Materials Characterization Papers. We also request comment, with supporting data, on any unidentified non-hazardous secondary fuel and/or ingredient materials used in combustion units.

IV. What Is the History of the Definition of Solid Waste Rules?

A. Statutory Definition of Solid Waste

RCRA defines “solid waste” as “* * * any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and *other discarded material* * * * resulting from industrial, commercial, mining, and agricultural operations, and from community activities * * *” (RCRA section 1004 (27) (emphasis added)). The key concept is that of “discard” and, in fact, this definition turns on the meaning of the phrase, “other discarded material,” since this term encompasses all other examples provided in the definition.

B. Solid Waste Program, RCRA Subtitle D

The regulations that pertain to non-hazardous solid waste (RCRA Subtitle D) contain five definitions of the term “solid waste.” (See 40 CFR 240.101(y); 40 CFR 243.101(y); 40 CFR 246.101(bb); 40 CFR 257.2; and 40 CFR 258.2.) These

regulatory definitions largely mirror the statutory definition of solid waste with some clarifications applicable to the specific regulatory section. The RCRA statutory definition of solid waste has also been repeated in the CAA emission guidelines for other solid waste incineration units (e.g., see 40 CFR 60.2977 and 60.3078).

EPA has not focused on the specific parameters of the definition of solid waste as it applies to non-hazardous solid waste programs under RCRA Subtitle D primarily because while, under RCRA Subtitle D, EPA promulgates criteria for municipal solid waste landfills and approves state solid waste landfill permitting programs, it is the states that fully implement those programs. EPA does not have the same role in these programs as it does in the hazardous waste programs established under RCRA Subtitle C. As a result, EPA has not promulgated detailed regulations of what is included in the definition of solid waste for the Subtitle D (non-hazardous) programs. States have promulgated their own laws and regulations regarding what constitutes solid waste and have interpreted those laws and regulations to determine what types of secondary materials management activities constitute discard (and therefore involve the management of a solid waste). However, EPA now needs to articulate which non-hazardous secondary materials constitute solid wastes under RCRA Subtitle D so that EPA can establish appropriate standards under CAA sections 112 and 129 for units that combust secondary materials for the purposes of energy recovery or when used as an ingredient. We envision that a Subtitle D definition of solid waste that could result from this rulemaking effort would not impact/affect any other types of management activities for these materials, such as landfilling, composting, etc., and as such, would have no impact at the Federal level on the Subtitle D program.

C. Hazardous Waste Program, RCRA Subtitle C

The RCRA Subtitle C hazardous waste federal program has a long regulatory history in defining “solid waste” for purposes of the hazardous waste regulations. However, the 40 CFR 261.2 definition of solid waste explicitly applies only to wastes that also are hazardous for purposes of the Subtitle C regulations (see 40 CFR 261.1(b)(1)).

EPA emphasizes that it is not requesting comment on any of its Subtitle C regulations or on any of the issues involved in its hazardous waste regulations regarding whether

secondary materials are hazardous wastes for purposes of its RCRA Subtitle C regulations. The Agency is not reopening its hazardous waste regulations in any way whatsoever; EPA does not intend to respond to any comments directed to its hazardous waste regulations.

The following discussion provides the context in which EPA’s hazardous waste regulations exclude certain materials that would otherwise be hazardous waste from the definition of solid waste. In 40 CFR 261.2, EPA defines solid waste for purpose of the hazardous waste regulations as “any discarded material that is not excluded * * *” by other provisions of Part 261.

For context, however, the Agency describes its hazardous waste regulations and the exclusions, themselves. First, a “discarded material” is defined in relevant part as a hazardous material which is abandoned, recycled, or considered inherently waste-like. A hazardous material is considered to be “abandoned” if it is disposed of, burned or incinerated, or accumulated, stored, or treated before or in lieu of being disposed of, burned, or incinerated. A hazardous material is considered to be a solid waste when recycled (or when accumulated, stored or treated prior to recycling) if it is: (a) Used in a manner constituting disposal (i.e., placed on the land or used to produce products that are placed on the land); (b) burned for energy recovery or used to produce a fuel;⁴² (c) reclaimed; or (d) accumulated speculatively.

While 40 CFR 261.2 sets out the basic regulatory definition of solid waste as it applies to hazardous waste, the regulations also exclude a number of specific hazardous secondary materials from the 40 CFR 261.2 definition of solid waste, and therefore, from the hazardous waste regulations. In general, these exclusions involve hazardous secondary materials that are products, co-products, or intermediates or other hazardous secondary materials that are reused/recycled/returned to the original process or hazardous secondary materials that meet fuel specifications. For example, hazardous secondary materials are not solid waste when used or reused as ingredients to make a product (provided the material is not reclaimed), used or reused as effective substitutes for commercial products, or are returned to the original process

⁴² Commercial chemical products listed in 40 CFR 261.33 are not solid wastes if they themselves are fuels. Also, all commercial chemical products that are fuels are not solid waste, regardless of whether they are listed as a hazardous waste (see 50 FR 14219, April 11, 1985).

without first being reclaimed (40 CFR 261.2(e)(1)). In addition, EPA has developed many case-specific solid waste exclusions (see 40 CFR 261.4(a)). For example, hazardous secondary materials that are comparable fuels or comparable syngas fuels are excluded even when recycled by being burned for energy recovery. (See 40 CFR 261.4(a)(16).) Also, EPA has recently finalized revisions to the definition of solid waste specifying that hazardous secondary materials being reclaimed under the control of the generator and hazardous secondary materials being transferred for reclamation are not solid wastes, provided certain restrictions and conditions are met.⁴³

D. Case Law on Definition of Solid Waste

Partly because the interpretation of the definition of solid waste is the foundation of the hazardous waste regulatory program, there has been a great deal of litigation over the meaning of “solid waste” under RCRA Subtitle C. From these cases, a few key principles emerge which guide our thinking on the definition of solid waste.

First, the ordinary plain-English meaning of the term “discard” controls. See *American Mining Congress v. EPA*, 824 F.2d 1177 (D.C. Cir. 1987) (“AMC I”). The ordinary plain-English meaning of the term discarded means “disposed of,” “thrown away,” or “abandoned.” The court specifically rejected a more expansive meaning for discard that would encompass any materials “no longer useful in their original capacity” even if they were not destined for disposal. 824 F.2d at 1185–87. The Court further held that the term “discarded materials” could not include materials “* * * destined for beneficial reuse or recycling in a continuous process by the generating industry itself.” (824 F.2d at 1190).

Subsequent to AMC I, the court discussed the meaning of discard in particular cases. In *American Petroleum Institute v. EPA*, 906 F.2d 729 (D.C. Cir. 1990) (“API I”), the court rejected EPA’s decision not to regulate recycled air pollution control equipment slag based on an Agency determination that waste “ceases to be a ‘solid waste’ when it arrives at a metals reclamation facility because at that point it is no longer ‘discarded material.’” 906 F.2d at 740. Instead, the materials were part of a mandatory waste treatment plan for hazardous wastes prescribed by EPA and continued to be wastes even if

recycled. 906 F.2d at 741. Further, a material is a solid waste regardless of whether it “may” be reused at some time in the future. *American Mining Congress v. EPA*, 907 F.2d 1179 (D.C. Cir. 1990) (“AMC II”).

One of the more important holdings of a number of court decisions is that simply because a waste has, or may have, value does not mean the material loses its status as a solid waste. See *API I*, 906 F.2d at 741 n.16; *United States v. ILCO Inc.*, 996 F.2d 1126, 1131–32 (11th Cir. 1993); *Owen Steel v. Browner*, 37 F.3d 146, 150 (4th Cir. 1994). *ILCO* and *Owen Steel*, however, seem to recognize that products made from wastes are, themselves, products and not wastes.

Association of Battery Recyclers v. EPA, 208 F.3d 1047 (D.C. Cir. 2000) (“ABR”) reiterated the concepts discussed in the previous cases. The Court held that it had already resolved the issue presented in ABR in its opinion in AMC I, where it found that “* * * Congress unambiguously expressed its intent that ‘solid waste’ (and therefore EPA’s regulatory authority) be limited to materials that are ‘discarded’ by virtue of being disposed of, abandoned, or thrown away” (208 F.2d at 1051). It repeated that materials reused within an ongoing industrial process are neither disposed of nor abandoned (208 F.3d at 1051–52). It explained that the intervening API I and AMC II decisions had not narrowed the holding in AMC I (208 F.3d at 1054–1056).

Notably, the Court did not hold that storage before reclamation automatically makes materials “discarded.” Rather, it held that “* * * at least some of the secondary material EPA seeks to regulate as solid waste (in the mineral processing rule) is destined for reuse as part of a continuous industrial process and thus is not abandoned or thrown away” (208 F.3d at 1056). In this regard, the court criticized all parties in the case—industry as well as EPA—because they “presented this aspect of the case in broad abstraction, providing little detail about the many processes throughout the industry that generate residual material of the sort EPA is attempting to regulate * * *.” (Ibid).

American Petroleum Institute v. EPA, 216 F.3d 50, 55 (D.C. Cir. 2000) (“API II”), decided shortly after ABR and considered by the court at the same time, provides further guidance for defining solid waste, but in the context of two specific waste streams in the petroleum refining industry. The court overturned EPA’s determination that certain recycled oil bearing wastewaters are wastes (216 F.3d at 55–58) and upheld conditions imposed by the

Agency in excluding petrochemical recovered oil from the definition of solid waste (216 F.3d at 58–59). In the case of oil-bearing wastewaters, EPA had determined that the first phase of treatment, primary treatment, results in a waste being created. 216 F.3d at 55. The court overturned this decision and remanded it to EPA for a better explanation, neither accepting EPA’s view nor the contrary industry view. The court noted that the ultimate determination that had to be made was whether primary treatment is simply a step in the act of discarding? Or is it the last step in a production process before discard? 213 F.3d at 57. In particular, the court rejected EPA’s argument that primary treatment was required by regulation, instead stating that the Agency needed to “set forth why it has concluded that the compliance motivation predominates over the reclamation motivation” and “why that conclusion, even if validly reached, compels the further conclusion that the wastewater has been discarded.” 213 F.3d at 58.

The court also considered whether material is discarded in *Safe Food and Fertilizer v. EPA*, 350 F.3d 1263 (D.C. Cir. 2003) (“Safe Food”). In that case, among other things, the court rejected the argument that, as a matter of plain meaning, recycled material destined for immediate reuse within an ongoing industrial process is never considered “discarded,” whereas material that is transferred to another firm or industry for subsequent recycling must always be solid wastes. 350 F.3d at 1268. Instead, the court evaluated “whether the agency’s interpretation of * * * ‘discarded’ * * * is, reasonable and consistent with the statutory purpose. * * *” *Id.* Thus, EPA has the discretion to determine if material is not a solid waste, even if it is transferred between industries.

We also note that the Ninth Circuit has specifically found that non-hazardous secondary materials may, under certain circumstances, be burned and not constitute a solid waste under RCRA. See *Safe Air For Everyone v. Waynemeyer* (“Safe Air”), 373 F.3d 1035 (9th Cir., 2004) (Kentucky bluegrass stubble may be burned to return nutrients to the soil and not be a solid waste).

E. Regulatory Interpretations Regarding the Recycling of Hazardous Secondary Materials and the Concept of Legitimacy

As over twenty-five years of experience in implementing the hazardous waste regulations has demonstrated, drawing the line between materials that are part of a

⁴³ See “Revisions to the Definition of Solid Waste,” Final Rule, October 30, 2008, at 73 FR 64667.

manufacturing process or are more commodity-like rather than waste-like (and therefore not discarded) from those that are discarded (and therefore are being disposed) is a difficult one and depends on a number of factors, including how the materials are managed.

For example, it is clear that the distillation of hazardous waste solvents or the neutralization of contaminated acids (while the hazardous secondary material itself may be regulated under the RCRA hazardous waste regulations) can produce products which are not considered wastes. Similarly, under 40 CFR 260.31(c), EPA may grant a variance from classifying as a solid waste those hazardous secondary materials that have been reclaimed, but must be reclaimed further. In order for such a variance to be granted, the resulting material must be commodity-like (even though it may not be a commercial product) based on a series of specific factors. Under one such variance, World Resources Company (WRC) accepts shipments of metal bearing sludges (principally sludges from electroplating operations, a listed hazardous waste under RCRA), and then dries and blends the sludges with other shipments to achieve concentrates that meet the contractual specifications of its customers (smelters that recover metals contained in the concentrates). Under the variance, the incoming electroplating sludges are regulated as hazardous waste until they are processed, but the resulting product is no longer a solid waste, and it can be shipped to smelters for further reclamation as a product in commerce and not as a waste. EPA is aware that several authorized states have made comparable determinations, as part of the state authorized RCRA hazardous waste program.

An important element under the RCRA Subtitle C definition of solid waste is the concept of legitimate recycling, including the legitimate use of hazardous secondary materials. Under RCRA Subtitle C, some hazardous secondary materials that would otherwise be subject to regulation under RCRA's "cradle to grave" system are not considered solid wastes if they are "legitimately recycled" or legitimately used as an ingredient or substitute for a commercial product. The principal reasoning behind this construct is that use or recycling of such materials often closely resembles normal industrial production, rather than waste management. However, since there can be considerable economic incentive to manage recyclable materials outside of the RCRA hazardous waste

regulatory system, there is a clear potential for and historical evidence of some handlers claiming they are recycling, when in fact they are conducting waste treatment and/or disposal in the guise of recycling. EPA considers such "sham" recycling to be, in fact, discard and materials being sham recycled to be solid wastes.

To guard against hazardous secondary materials being discarded in the guise of recycling, EPA has long articulated the need to distinguish between "legitimate" (i.e., true) recycling and "sham" (i.e., fake) recycling, beginning with the preamble to the 1985 hazardous waste regulations that first established the definition of solid waste under RCRA Subtitle C (50 FR 638; January 4, 1985). A similar discussion that addressed legitimacy as it pertains to burning hazardous secondary materials for energy recovery (considered a form of recycling under RCRA Subtitle C) was presented in the January 9, 1988 proposed amendments to the definition of solid waste (53 FR 522). On April 26, 1989, the Office of Solid Waste issued a memorandum that consolidated the various preamble and other statements concerning legitimate recycling into a list of questions to be considered in evaluating the legitimacy of a hazardous secondary materials recycling process (OSWER directive 9441.1989(19)). This memorandum (known to many as the "Lowrance Memo") has been a primary source of information for the regulated community and for overseeing agencies in distinguishing between legitimate and sham recycling.

As discussed above, on October 30, 2008, EPA finalized several exclusions from the definition of solid waste for hazardous secondary materials being reclaimed and a non-waste determination process for persons to receive a formal determination that their hazardous secondary materials are not solid wastes when legitimately reclaimed. As part of that final rule, EPA codified a legitimate recycling provision specifically as a condition of these exclusions and the non-waste determination process.

As discussed earlier, EPA emphasizes that it is not requesting comment on any Subtitle C regulation or any of the issues involved in its hazardous waste regulations. EPA does not intend to respond to any comments directed to its hazardous waste regulations.

However, because the concept of legitimacy is a useful one in determining when a secondary material is genuinely recycled and not discarded under the guise of recycling, the Agency is including the following discussion in

today's preamble to provide the context in which EPA has integrated the concept of legitimacy into the latest hazardous waste exclusions from the definition of solid waste.

The legitimacy provision in the October 2008 final rule, which applies specifically to the hazardous secondary materials excluded under the rule, has two parts. The first part includes two factors: (1) The hazardous secondary materials being recycled must provide a useful contribution to the recycling process or to the product or intermediate of the recycling process, and (2) the product or intermediate produced by the recycling process must be valuable. These two legitimacy factors make up the core of legitimacy, and, therefore, a process that does not conform to them cannot be a legitimate recycling process, but would be considered sham recycling.

The second part of the legitimacy provision consists of two factors that must be considered when determining if a particular hazardous secondary material recycling process is legitimate for the purposes of the exclusion. These two factors are: (1) The generator and the recycler should manage the hazardous secondary material as a valuable commodity, and (2) the product of the recycling process does not contain significant concentrations of hazardous constituents that are not in analogous products. EPA believes these two factors are important in determining legitimacy, but has not made them factors that must be met because the Agency is aware that a legitimate recycling process may not conform to one or both of these two factors. In making a determination that a hazardous secondary material is legitimately recycled, persons must evaluate all factors and consider legitimacy as a whole. If, after careful evaluation of these other considerations, one or both of the non-mandatory factors are not met, then this fact may be an indication that the material is not legitimately recycled. To evaluate the extent to which these factors are met and in determining the legitimacy of a recycling process that does not meet one or both of these factors, persons can consider the protectiveness of the storage methods, exposure from toxics in the product, the bioavailability of the toxics in the product, and other relevant considerations.

EPA stated in the preamble to the October 2008 final rule that, although the Agency was only codifying the legitimacy provision as part of the new hazardous secondary materials recycling exclusions and non-waste determination process, it was stressing that EPA

retains its long-standing policy that all recycling of hazardous secondary materials must be legitimate and that the four legitimacy factors codified at 40 CFR 260.43 are substantively the same as the existing legitimacy policy, as stated in the 1989 Lowrance Memo and in various definitions of the solid waste rulemakings.

The same principle of "legitimacy" is likewise an important element in the recycling of non-hazardous secondary materials. That is, the concept of legitimate recycling is crucial to determining whether a non-hazardous secondary material being recycled is truly being recycled or is, in fact, being discarded through sham recycling. In this notice, the Agency is addressing the same basic concept of legitimate recycling by discussing when a non-hazardous secondary material that is not discarded is legitimately recycled or is a legitimate ingredient in an industrial process. Obviously, a secondary material that is not discarded and is combusted can only be a fuel or ingredient, and not a solid waste, if the material is being legitimately used as a fuel or ingredient.

Consequently, the Agency is seeking comment on the appropriate construct for determining when non-hazardous secondary materials are legitimately burned as fuel or used as a legitimate ingredient in an industrial process. This is explained in detail in the following Section V: Preliminary EPA Approach to Determine if Materials Are Considered Solid Wastes.

V. Preliminary EPA Approach To Determine if Materials Are Considered Solid Wastes

A. Materials That Are Not Solid Wastes

EPA is providing advanced notice of its intent to develop a definition of the term "solid waste" under RCRA for non-hazardous secondary materials that are used as a fuel or ingredient in a manufacturing process. As noted previously, the purpose of this notice is to assist EPA in developing emissions standards under sections 112 and 129 of the CAA, because the CAA states that the term "solid waste" shall have the meaning "established by the Administrator pursuant to [RCRA]." 42 U.S.C. 7429(g)(6). The Agency is considering various usage of secondary materials (e.g., as fuels or ingredients) and whether these materials should be considered solid wastes under RCRA when used in combustion devices, such that burning these materials would be subject to regulation under CAA section 129, rather than potentially subject to CAA section 112. EPA has

identified several cases where we believe secondary materials are not solid wastes when combusted. These include:

- Traditional fuels;
- Secondary materials used as legitimate "alternative" fuels that have not been previously discarded;
- Secondary materials used as legitimate "alternative fuels" resulting from processing of discarded secondary materials;
- Secondary materials used as legitimate ingredients; and
- Hazardous secondary materials that may be excluded from the definition of solid waste under RCRA Subtitle C because they are more like commodities than wastes.

1. Traditional Fuels

Fossil fuels (e.g., coal, oil, natural gas), and their derivatives (e.g., petroleum coke, bituminous coke, coal tar oil, refinery gas, synthetic fuel, heavy recycle, asphalts, blast furnace gas, recovered gaseous butane, coke oven gas), as well as cellulosic biomass (e.g., wood) are traditional fuels which have been burned historically as fuels and have been managed as valuable products. These traditional fuels are unused products that have not been discarded and therefore are not solid wastes. (However, certain "alternative" fuels, such as coal refuse, have in some cases been abandoned, and therefore discarded—see discussion of coal refuse in section VI.A.) EPA also believes that wood collected from forest fire clearance activities and trees and uncontaminated wood found in hurricane debris is not discarded if managed properly and burned as a legitimate fuel, and therefore is not a solid waste. We request comment on whether there are other traditional fuels that would fall within this grouping.

It should be understood that cellulosic biomass, as described above, includes unadulterated or clean wood, but that other forms of wood, such as reconstituted wood/panel products (e.g., medium density fiberboard, particle board, and laminated lumber) or painted and chemically treated wood, would need to be evaluated as to whether they would qualify as a legitimate alternative fuel pursuant to the criteria described in the following section.

2. Guiding Principles Used To Determine if Secondary Materials Used in Combustion Units Are Solid Wastes

For these various secondary materials that are used either as ingredients or alternative fuels, EPA is examining the principles expressed in the various court decisions on previous

rulemakings. In addition, we are considering the overall principle in our hazardous waste regulations that materials treated as a commodity, rather than as a waste, are not discarded and are not solid wastes so long as they are legitimately recycled. We are soliciting comments on the appropriateness of the principles as applied to non-hazardous secondary materials and on how best to structure the criteria for when a non-hazardous secondary material is or is not a solid waste. To this end, the same secondary material could be a solid waste or not depending on how it has been handled and managed because handling and management factors into whether or not the secondary material has been discarded. Key factors in determining if these alternative fuels or ingredients are solid wastes under RCRA are: (1) Whether they have been discarded, which includes how they are managed and whether they are being used as legitimate fuels and ingredients; and (2) if they have been discarded, whether they have been processed to produce a fuel or ingredient product that would not be considered a solid waste.

As noted above in the discussion of AMC I, as well as other consistent cases, the plain-English meaning of the term discard applies to the RCRA definition of solid waste. That is, a material is discarded if it is disposed of, thrown away, or abandoned. Moreover, the term "discarded materials" could not include materials " * * * destined for beneficial reuse or recycling in a continuous process by the generating industry itself."

Determining whether a secondary material is used in a continuous process is important because certain materials under consideration are produced and managed in a continuous process within an industry (e.g., bagasse and cement kiln dust that is recycled in cement kilns). In looking at the recently promulgated Subtitle C non-waste determination petition process under 40 CFR 260.34, to determine whether hazardous secondary materials are used in a continuous process, EPA would evaluate whether the hazardous secondary material is part of the continuous primary production process and is not waste treatment. If the hazardous secondary material is handled in a manner identical to virgin feedstock, then it would appear to be fully integrated into the production process. At the other end of the spectrum, however, hazardous secondary materials indisputably discarded prior to being reclaimed are not a part of the continuous primary production process. See *API I, ILCO* and

Owen Steel, cited previously. Moreover, hazardous secondary materials are likely discarded in the case where industry may reuse materials in the future and it is not clear that reuse will occur. See *AMC II*, cited previously. By similar logic, EPA believes that non-hazardous alternative fuels or ingredients that are produced and used as a legitimate fuel or ingredient in a continuous process would not be considered to have been discarded.

Furthermore, even if the material is not used in a continuous process, if it is used as a legitimate fuel or ingredient, these secondary materials are likely not solid wastes if they were not previously discarded. See *API II* and *Safe Food*, previously cited. Many materials, such as coal fly ash and biomass are intended for legitimate reuse and therefore are not discarded. EPA believes these materials, if used as legitimate fuels or ingredients (as discussed in more detail below) would likely not be solid wastes if they have not been previously discarded (however, as discussed later in this section, previously discarded materials that are processed into a legitimate fuel product or ingredient would also likely not be solid wastes).

However, for alternative fuels or ingredients to not be considered discarded, and thus not solid wastes, they must be legitimate fuels or ingredients. Below we first discuss the legitimacy criteria for alternative fuels, followed by a discussion of the legitimacy criteria for materials used as ingredients.

a. Legitimate Alternative Fuels.

Specifically, the Agency generally considers secondary materials to be a legitimate fuel if they are handled as valuable commodities, have meaningful heating value, and contain contaminants that are not significantly higher in concentration than traditional fuel products. If these criteria are not met, sham recycling may be indicated and the secondary material might be a solid waste. EPA is interested in receiving comments on these principles. Specifically:

- **Handled as a Valuable Commodity.** For hazardous secondary materials, EPA has previously said, with respect to whether something is managed as a valuable commodity, that where there is an analogous raw material, the hazardous secondary material should be managed, at a minimum, in a manner consistent with the management of the analogous raw material.⁴⁴ Where there is no analogous raw material, the

hazardous secondary material should be contained. Hazardous secondary materials that are released to the environment and are not recovered immediately are considered to be discarded. We request comment on whether similar criteria should be used to determine if non-hazardous secondary materials used as alternative fuels are being managed as valuable commodities and thus are not solid waste, or whether more tailored criteria are more appropriate for non-hazardous secondary materials. For example, in situations where there is no analogous raw material, the Agency is interested in what type of containment would be necessary for non-hazardous secondary materials, particularly whether materials that are physically solid, such as tires, require containment.

- **Meaningful Heating Value:** EPA is seeking comment on how to define meaningful heating value for materials that are used as alternative fuels. Because of the wide variety of materials in question, and because of technology advances and the fact that fuel values vary, EPA questions whether it is possible or appropriate to establish a specific heating value cutoff for "legitimate" fuel. In the context of the hazardous waste regulations, EPA addressed the concept of whether a hazardous secondary material has an adequate, meaningful heating value in the so-called "comparable fuels" rule (63 FR 33781) with a benchmark Btu content of 5,000 Btu/lb (see section V.A.6 for more on the comparable fuels rule).⁴⁵ However, given improved combustion processes that have been developed that cost-effectively produce energy from lower rank materials (e.g., circulating fluidized bed combustion units), and given the fact that lower Btu content non-hazardous materials are frequently combusted for fuel value, EPA is requesting comment on whether a Btu content is needed, and if so whether a lower Btu content may be appropriate. Alternative fuel materials have a wide range of heating values that range from 2,600 Btu/lb for food; to 3,000 Btu/lb for yard trimmings; to 3,750 Btu/lb for sludge; to 5,000 Btu/lb for wood; and to 13,450 BTU/lb for rubber.⁴⁶ We request comment on

⁴⁵ In addition, EPA has previously stated that Subtitle C industrial furnaces (i.e., cement kilns and industrial boilers) burning wastes with energy value greater than 5,000 Btu may generally be said to be burning for energy recovery, however, lower energy wastes could conceivably be burned for energy recovery due to the devices' general efficiency of combustion. "Thus, the 5,000 Btu level is not an absolute measure of burning for energy recovery * * *." (see 62 FR 24251, May 2, 1997).

⁴⁶ See background document titled "Methodology for Allocating Municipal Solid Waste to Biogenic

whether we should develop a specific minimum Btu value on an "as-fired" basis that would qualify a secondary material as having meaningful heating content, or whether we should define meaningful heating value more qualitatively based on general principles.

- **Presence of Non-fuel Contaminants:** In the hazardous waste comparable fuels rule, EPA established numerical specifications for toxic organics, toxic metals, sulfur, nitrogen, halogens, and polychlorinated biphenyls (PCBs). To address the possible presence of waste-like contaminants in non-hazardous secondary materials, EPA believes a qualitative approach is more appropriate and can be used to identify waste materials containing contaminants that are significantly higher in concentration than those contained in traditional fuel products to the degree that sham recycling is indicated. The term "contaminants" refers to constituents in secondary materials that may be of a concern when burned as a fuel. For example, secondary materials that could contain contaminants that are significantly higher in concentration than those contained in traditional fuel products include chromium-, copper-, and arsenic (CCA)-treated lumber, secondary mill residues (i.e., residues such as board, trim and breakage from the manufacture of reconstituted wood/panel products), polyvinyl chloride (PVC) plastics which can contain 60 percent halogens (chlorine),⁴⁷ lead-based painted wood, fluorinated plastics, and non-hazardous halogenated solvents. In determining whether the concentration of contaminants in secondary materials is "significantly higher," the Agency could include a qualitative evaluation of the potential human health and environmental risks posed. A contaminant concentration could be elevated without posing unacceptable risk, and therefore may not be considered "significant" for the purposes of determining whether the secondary material is a legitimate fuel. We request comment on whether a qualitative approach to defining fuels as solid waste because they are too contaminated (indicating sham recycling) is an appropriate option. In any case, given the multiplicity of fuel materials, we believe that numerical specifications are likely to be

and Non-Biogenic Energy, Energy Information Administration (U.S.DOE), May, 2007.

⁴⁷ Constituents, such as chlorine in PVC are relevant because of the potential for chlorinated combustion by-products to be emitted (e.g., dioxins, hydrogen chloride).

⁴⁴ See "Revisions to the Definition of Solid Waste," Final Rule, October 30, 2008, at 73 FR 64667.

impractical. We also request comment on whether the contaminants evaluated for the comparable fuels rule,⁴⁸ which mostly includes Appendix VIII constituents, should also be used for non-hazardous secondary materials used as fuels, or whether a different list of contaminants is appropriate.

b. Legitimate Alternative Ingredients. For non-hazardous secondary materials to be used as legitimate ingredients, the Agency would use a similar legitimacy analysis as was developed in the hazardous waste program. Specifically, the Agency would generally consider secondary materials to be a legitimate ingredient if the secondary material is handled as a valuable commodity, the secondary material provides a useful contribution, the recycling results in a valuable product, and the product does not contain contaminants that are significantly higher in concentration than traditional products. If these criteria are not met, sham recycling may be indicated and the secondary material may be a solid waste. For use as an ingredient, EPA would not be looking at fuel value since the secondary materials are being used as an ingredient and not a fuel. Instead, the Agency would look at useful contribution and valuable product, as described below. The Agency is interested in receiving comments on these principles, including whether the following principles are reasonable for non-hazardous secondary materials used as ingredients:

- **Handled as a Valuable Commodity.** For hazardous secondary materials, EPA has previously said, with respect to whether a secondary material is managed as a valuable commodity, that where there is an analogous raw material, the hazardous secondary material should be managed, at a minimum, in a manner consistent with the management of the analogous raw material. Where there is no analogous raw material, the hazardous secondary material should be contained. Hazardous secondary materials that are released to the environment and are not recovered immediately are discarded, and thus would be regarded as a waste and not a commodity. We request comment on whether similar criteria should be used to determine if non-hazardous secondary materials used as ingredients are being managed as valuable commodities and thus are not solid waste, or whether more tailored criteria are more appropriate for non-hazardous secondary materials.

- **Useful Contribution:** For hazardous secondary materials, EPA has previously stated that a secondary material must provide a useful contribution to the recycling process or to the product of the recycling process.⁴⁹ The ways in which a secondary material can add value and usefully contribute to a recycling process are: (i) The secondary material contributes valuable ingredients to a product or intermediate; or (ii) replaces a catalyst or carrier in the recycling process; or (iii) is the source of a valuable constituent recovered in the recycling process; or (iv) is recovered or regenerated by the recycling process; or (v) is used as an effective substitute for a commercial product. We request comment on whether this description is applicable for non-hazardous secondary materials used as ingredients in a combustion process.

- **Valuable Product or Intermediate:** Similarly, for hazardous secondary materials, EPA has stated that the recycling process must produce a valuable product or intermediate.⁵⁰ The Agency believes a product or intermediate is valuable if it is (i) sold to a third party or (ii) used by the recycler or generator as an effective substitute for a commercial product or as an ingredient or intermediate in an industrial process. The Agency believes this description is broad enough to incorporate both products that are valuable from a monetary standpoint and products or intermediates that have intrinsic value to the generator or the recycler. We are seeking comment on whether this description of valuable product/intermediate is an appropriate way to consider this criterion in the context of non-hazardous secondary materials used as ingredients.

- **Presence of Contaminants:** As mentioned above under legitimate fuel criteria, EPA is suggesting a qualitative approach may be more appropriate to use in identifying waste materials containing contaminants that are significantly higher in concentration than those contained in traditional products to the degree that sham recycling is indicated. In the context of hazardous secondary materials, EPA expects those making a legitimate recycling determination to look at the concentrations of hazardous constituents found in the product made from hazardous secondary materials and compare them to the concentrations of

hazardous constituents in analogous products to determine if the concentrations are significantly higher.⁵¹ In determining whether the concentration of contaminants in secondary materials is “significantly higher,” the Agency could include a qualitative evaluation of the potential human health and environmental risks posed. A contaminant concentration could be elevated without posing unacceptable risk, and therefore may not be considered “significant” for the purposes of determining whether the secondary material is a legitimate ingredient. EPA concluded in the most recent hazardous secondary material rulemaking that the complexities of defining “significant” via a bright-line quantitative test that would also still be appropriate for all industries, all recycling processes, and all recycled hazardous secondary materials were too great for the Agency to be able to design as a simple and straightforward system of tests to be used in making such determinations.⁵² We request comment on whether a similar qualitative approach to defining ingredients used in a manufacturing process involving combustion as solid waste because they are too contaminated (indicating sham recycling) is the preferred option or whether numerical specifications is a better approach. In addition, the Agency is requesting comment on whether the contaminants evaluated should be the hazardous constituents listed in Appendix VIII to 40 CFR Part 261 or whether a different list of contaminants is more appropriate for non-hazardous secondary materials used as ingredients.

c. Discarded Secondary Materials That Have Been Processed. In many cases, the secondary material may have been discarded, but later processed to produce a legitimate fuel product or ingredient, ready for direct use in an industrial process. In such cases, the processed material that is extracted or reclaimed as a legitimate fuel or ingredient would not be a waste, but rather a product of the processing activity. In general, the products from the recycling of solid wastes are not themselves wastes—for example, paper that is made from recycling used paper and then sold in stores is a product, not a waste. EPA believes that if a secondary material is processed into a legitimate fuel or ingredient material, the processed material would not be a discarded material. Of course, these

⁴⁹ See “Revisions to the Definition of Solid Waste,” Final Rule, October 30, 2008, at 73 FR 64667.

⁵⁰ See “Revisions to the Definition of Solid Waste,” Final Rule, October 30, 2008, at 73 FR 64667.

⁵¹ See “Revisions to the Definition of Solid Waste,” Final Rule, October 30, 2008, at 73 FR 64667.

⁵² See “Revisions to the Definition of Solid Waste,” Final Rule, October 30, 2008, 73 FR at 64745.

⁴⁸ See RCRA Comparable Fuel Exclusion Final Rule, June 19, 1998 at 40 CFR 261.38.

products still must qualify as legitimate fuels or ingredients, as previously discussed. Otherwise, sham recycling may be indicated and the materials may be a solid waste. For example, used oil that is processed to produce “on-spec fuel” and that meets the standards of 40 CFR 279.11 would be considered a product, not a waste. See section V.A.4 for more discussion of used oil.

In the following sections, we discuss three groupings (previously listed) where we believe secondary materials are not solid wastes, but rather are non-discarded products that are legitimate fuels or ingredients when used in combustion units. We are soliciting comment on our interpretation of these materials as not being solid wastes under RCRA.

3. Secondary Materials Used as Legitimate “Alternative” Fuels That Have Not Been Previously Discarded

As we discussed previously, EPA believes that the question of what constitutes a legitimate “fuel” reflects the availability of fuel materials generally, the demand for fuel, and technology developments. Thus, in addition to traditional fuels, the Agency also believes that there is a category of secondary materials that are legitimate alternative fuels; that is, there are secondary materials that may not have been traditionally used as fuels, but that are nonetheless legitimate fuels today because of changes in technology and in the energy market. In cases where these legitimate alternative fuels have not been discarded, EPA would not consider them to be solid wastes.

Alternative fuels consisting of biomass represent a large percentage of the alternative fuels in use today. We generally believe that much of the biomass currently used as alternative fuels are not solid waste since they have not been discarded in the first instance and are legitimate fuel products (i.e., they have been managed as valuable commodities, have meaningful heating value and do not contain contaminants that are significantly higher in concentration than those in traditional fuel products). Thus, when burned, it would not be considered “sham” combustion. See previous discussion in section V.A.2. Biomass can include a wide range of alternative fuels, and can be broken down into two different categories—cellulosic biomass and non-cellulosic biomass. Cellulosic biomass includes forest-derived biomass (e.g., green wood, forest thinnings, clean and unadulterated bark, sawdust, trim, and tree harvesting residuals from logging and sawmill materials), food scraps, and pulp and paper mill residuals (e.g.,

spent pulping liquors; hog fuel, such as clean and unadulterated bark, sawdust, trim screenings; and residuals from tree harvesting), and agricultural residues (e.g., straw, corn husks, peanut shells, and bagasse). Non-cellulosic biomass includes manures and gaseous fuels (e.g., from landfills and manures).

EPA generally considers biomass as described above, especially cellulosic biomass, to have comparable composition when compared to traditional fuel products due to the nature of the plants and animals (i.e., they would not be considered to have additional “contaminants”). Thus, if they are managed as valuable commodities and have meaningful heating value, then we do not believe that they should be considered solid wastes. We request comment on whether biomass as described above contains contaminants that are significantly higher in concentration when compared to traditional fuel products. In determining whether the concentration of contaminants in biomass is “significantly higher,” the Agency could include a qualitative evaluation of the potential human health and environmental risks posed. A contaminant concentration could be elevated without posing unacceptable risk, and therefore may not be considered “significant” for the purposes of determining whether the secondary material is a legitimate fuel. We also request comment on the impact of a solid waste determination, one way or the other, on the inclusion of biomass materials in the many state-initiated renewable fuels specifications whereby such materials (e.g., manures, forest thinnings) are required to be used in the electric generation portfolio within the state.

EPA also believes that tires used as TDF, which include whole or shredded tires, that have not been previously discarded, are legitimate fuels that meet our previous described criteria (i.e., they are handled as valuable commodities, have meaningful heating value, and do not contain contaminants that are significantly higher in concentration when compared to traditional fuel products). EPA’s 1997 study on “Air Emissions from Scrap Tire Combustion”⁵³ concluded that potential emissions from TDF are often

⁵³ This study was published by EPA’s Office of Research and Development and produced as part of EPA’s National Risk Management Research Laboratory strategic long-term research plan for the prevention and control of pollution to air, land, water, and subsurface resources; protection of water quality in public water systems; remediation of contaminated sites and groundwater; and prevention and control of indoor air pollution.

less than and generally within the same range as, emissions from conventional fossil fuels. Thus, if the tires have not been abandoned and thrown away, we would not consider them to be solid wastes. For example, approximately 130 million tires per year are obtained from tire dealerships and used directly as a fuel. In many cases, these tires are collected pursuant to state tire programs and handled as valuable products, and, therefore, they have not been abandoned, disposed of, or thrown away.⁵⁴ In other cases, they are transferred to brokers or directly to industrial operations through standard commercial transactions. In contrast, tires that have accumulated in tire piles over the years (i.e., those tires in tire piles that have been abandoned) have been discarded, and thus considered to be solid waste (although they may later be processed into a legitimate fuel product).⁵⁵

Other non-traditional alternative fuels in use today that we are evaluating to determine whether they have not been discarded, and are legitimate alternative fuels include construction and demolition materials, scrap plastics, non-hazardous non-halogenated solvents and lubricants, and wastewater treatment sludge. We request comment on whether these secondary materials are legitimate alternative fuels and thus would not be solid wastes if they have not been previously discarded. Commenters should provide data and/or information supporting whether these secondary materials are legitimate and whether they are or are not considered to have been discarded.

Some secondary materials are questionable as to whether they are legitimate fuels because they lack adequate heating value, which could be the case for wet biomass that has insufficient as-fired heating content due to its moisture content. Another secondary material that may not be a legitimate fuel is biomass that has, for example, undergone chemical treatment, such that the material may contain contaminants that are significantly higher in concentration than those in traditional fuel products to

⁵⁴ States typically regulate these programs under their state solid waste authorities. It is not the Agency’s intent to undercut state authorities in this area. We request comment on whether tires collected pursuant to state tire programs have been discarded. We also request comment on whether an EPA designation specifying that used tires, for example, managed pursuant to state collection programs are not solid wastes, would adversely impact a states ability to manage such programs. This similarly would apply to used oil as well.

⁵⁵ For example, as noted below, whole tires can be processed (shredded) into fuel products after they have been discarded.

the degree that sham recycling is indicated. Secondary materials that we think may contain contaminants that are significantly higher in concentration than those of traditional fuel products include PVC (which can contain 60 percent chlorine),⁵⁶ halogenated plastics, chromated copper arsenate (CCA) lumber, creosote lumber, copper-based treated lumber, lead-based treated lumber, secondary mill residues (i.e., residues such as board, trim and breakage from the manufacture of reconstituted wood/panel products), and non-hazardous halogenated solvents. In determining whether the concentration of contaminants in secondary materials is “significantly higher,” the Agency could include a qualitative evaluation of the potential human health and environmental risks posed. A contaminant concentration could be elevated without posing unacceptable risk, and therefore may not be considered “significant” for the purposes of determining whether the secondary material is a legitimate fuel. We request comment on whether these secondary materials contain contaminants that are significantly higher in concentration compared to traditional fuel products, and whether there are other secondary materials not listed that should be considered to have contaminant concentrations that would result in them being disqualified as a legitimate fuel (i.e., a solid waste when burned).

We also request comment on whether there are other types of secondary materials that should be considered alternative fuels, assuming they have not been discarded and are legitimate (i.e., they meet the criteria discussed in section V.A.2). For example, as we discuss in more detail in section VI, biofuel production has increased dramatically in the past few years and is expected to continue increasing over the coming years. We later take specific comment on the extent to which biofuels are currently used in stationary combustion units, and the extent to which byproducts from the production of biofuels, as well as ingredients used to produce biofuels, such as fats, oils, and greases, are used directly in stationary combustion units as alternative fuel sources. Commenters should explain the circumstances under which these secondary materials would not be considered to have been

discarded, and how these materials meet the criteria as legitimate fuels. See the Materials Characterization Papers in the docket established for this ANPRM for a complete description of the secondary materials EPA is assessing as part of this effort.

4. Secondary Materials Used as Legitimate “Alternative Fuels” Resulting From the Processing of Discarded Secondary Materials

EPA also believes that legitimate fuel products may be extracted, processed, or reclaimed from non-hazardous secondary materials that have been discarded in the first instance and that such products would generally not be considered solid waste. Once processed to make a legitimate fuel product, such a product would not be discarded and therefore would not be a solid waste, provided it met the general principles previously discussed for being a legitimate fuel. (Note: Until a legitimate product has been extracted, processed or reclaimed, the secondary material that has been discarded is a solid waste.) The principle behind this idea of processing a waste to produce a product is common to industrial processes.

Due to the nature of some materials (e.g., low Btu value, the presence of contaminants, or the need for certain physical characteristics to address handling issues associated with the combustion device), processing will be necessary for the secondary material to be used as a fuel. Such discarded materials generally would be solid wastes until the point that a fuel product is produced; however, the fuel itself would not be a solid waste as long as it met the legitimacy factors. Secondary materials that can be processed into fuel include discarded biomass, coal fines, used oil, tires, and landfill ash. The degree of processing necessarily will vary depending on the specific material, but the objective remains the same—the product from the processing must be a legitimate fuel (i.e., a material with meaningful heating value, with contaminants that are not present at significantly higher concentrations than those of traditional fuel products, and managed as a valuable commodity). Below are some examples of secondary materials that we believe may be processed to produce a legitimate non-waste fuel.

- For biomass that has been previously discarded and has high moisture content, dewatering/drying techniques can be used to effectively increase the Btu/lb and produce a legitimate non-waste fuel, provided the biomass does not contain contaminants at significantly higher concentrations

and is handled as a valuable commodity.

- Wood with lead-based paint can be processed to remove the lead-based paint, leaving the underlying wood for use as a non-waste, traditional fuel, and the lead-based paint can then be safely disposed of or sent for lead recovery.

- Tires that cannot be handled whole by some combustion devices (whether discarded or not) can be processed by shredding and removing dirt or other contaminants to produce TDF. Turning scrap tires into TDF can involve two physical processing steps: chipping/shredding and in some cases metal removal. TDF consists of chipped tires ranging in size from 1 to 4 inches; the amount of metal in TDF varies depending on how much of the tires have been processed. Some units, such as cement kilns use the metal in the wire as a valuable ingredient in the manufacturing process, and therefore do not require its removal. However, most other units benefit from TDF that has been processed to minimize the amount of metal and improve heating efficiency. At this point, EPA considers tire shredding/chipping alone (without metal recovery), as well as in combination with metal recovery, as legitimate processing activities sufficient to convert a discarded material into a fuel product.

- Coal fines, biomass, and other materials can be mixed and processed into pellets (or other forms) that have the consistency and handling characteristics of coal (e.g., K-Fuel, N-Viro).

In all of the examples above, we, at this point, view the secondary material to have been sufficiently processed to produce a fuel that would not be a solid waste if it met the general principles described earlier—that is, the fuel product is a legitimate fuel and “sham” combustion (i.e., discard rather than use) has not occurred. Of course, any waste generated in the “processing” of these materials would need to be managed properly. We seek comment on whether the processing described above is sufficient to convert discarded material into a fuel product.

In addition to the examples above, we request comment on some additional operations that involve processing. Specifically, logging and primary milling residues may be chipped or sorted before combustion. Although we generally believe that this material would not be considered to have been discarded, we request comment on whether any forest-derived biomass that was determined to have been discarded and was subsequently processed by chipping or sorting prior to combustion

⁵⁶ As previously discussed, the term “contaminants” refers to constituents in secondary materials that may be of a concern when burned as a fuel. Constituents, such as chlorine in PVC are relevant because of the potential for chlorinated combustion by-products to be emitted (e.g., dioxins, hydrogen chloride).

would be considered to have undergone adequate processing to convert the discarded material into a fuel product. Mined landfill power plant ash can also be processed (e.g., crushed, screened, and/or separated into its fundamental components through density separation techniques) into a fuel. We also request comment on whether mined landfill ash is adequately processed to convert it into a fuel product or ingredient (under the assumption that it meets our previously described legitimacy criteria).

Used oil is a special case since it is specifically addressed in the RCRA statute (RCRA section 3014). It is worth noting that the statute does not define used oil as a solid waste. Section 3014 provides that EPA is to make a determination whether used oil is a hazardous waste, but is silent on whether used oil per se is a solid waste. Thus, we must apply the previously described criteria to determine if used oil is in fact discarded. Pursuant to RCRA section 3014, the Agency has promulgated standards for used oil management. The Standards for the Management of Used Oil in 40 CFR part 279 set forth management requirements for used oil that include contaminant limits to identify when used oil is considered to be "on-specification" used oil as opposed to "off-specification," and when it must be managed as a hazardous waste.

Table 1 in section 279.11 provides contaminant limits for "on-specification" used oil. On-specification used oil can only be burned for energy recovery, and once used oil is shown to meet the specification limits, the only requirement is maintenance of records of shipment to on-specification burners. No requirements or limitations are imposed on the management or burning of the on-specification used oil. Other uses of on-specification used oil would continue to cause that use to be subject to the used oil regulations. Management of used oil that does not meet the specification limits (referred to as off-spec used oil) is subject to the management controls, including recordkeeping, storage standards, and burning requirements. With one exception, off-spec used oil may only be burned in Subtitle C hazardous waste incinerators, or in boilers and industrial furnaces specified by the regulations (see 40 CFR 279.61). The exception is generators may burn off-spec used oil in used oil-fired space heaters provided that the heater burns only used oil that the owner or operator generates or used oil received from household do-it-yourself used oil generators, the heater is designed to have a maximum capacity

of not more than 0.5 million Btu per hour, and the combustion gases from the heater are vented to the ambient air.

There also is an upper total halogen limit for used oil (known as the rebuttal presumption). If the used oil has halogens in excess of 1,000 ppm, the used oil is considered to have been mixed with halogenated hazardous wastes, and must be managed as a hazardous waste unless a demonstration can be made that the used oil does not in fact contain hazardous waste.

We generally consider off-specification used oil that is collected from repair shops to have been originally discarded since this used oil contains both fossil fuel and contaminants picked up during use as a lubricant, and likely contains contaminants that are significantly higher in concentration than traditional fuels, and thus would not be considered a legitimate fuel per the criteria discussed in section V.A.2. However, if the fossil fuel component is extracted from the non-fuel contaminants through processing to meet the on-specification levels in 279.11, the resultant fossil fuel is not significantly different from traditional fossil fuels in every way and thus should be considered a product fuel, not a waste. We also consider used oil that is collected from repair shops that already meet the "on-spec" limits to be legitimate fuel products, not wastes.

We request comment on whether off-specification used oil managed pursuant to the 40 CFR 279 used oil management standards which are burned for energy recovery is considered to be discarded, and thus solid waste. Although off-specification used oil may contain contaminant levels that are higher in concentration than traditional (virgin) fossil fuels, they still are managed within the constraints of the used oil management standards, and may only be burned in specific types of combustion devices.

5. Secondary Materials Used as Legitimate Ingredients

For secondary materials used as ingredients, we also must determine whether the alternative ingredients have been discarded, which includes assessing how they are managed, and whether they are being used as legitimate ingredients pursuant to the criteria described in section V.A.2. Secondary materials that the Agency is assessing as alternative ingredients include CKD, bottom ash, boiler slag, blast furnace slag, foundry sand, and secondary glass material. We request comment on whether these secondary materials are legitimate ingredients as

previously described in section V.A.2 and thus would not be solid wastes if not previously discarded. Commenters should provide data and/or information supporting whether these secondary materials are legitimate ingredients and thus, whether they are or are not considered to have been discarded. For example, we believe that CKD is not a solid waste if it is recycled within the continuous clinker production process. We also believe that coal fly ash is handled as a commodity within continuous commerce when it is marketed to cement kilns as an alternative ingredient. As a result, if it is determined to be a legitimate ingredient pursuant to the criteria outlined in section V.A.2, we would not consider it to be a solid waste.

If the alternative ingredient was previously discarded, however, the Agency believes that such secondary materials are solid wastes, unless they were processed into a legitimate ingredient product. The Agency solicits comment on this situation (that is, the situation where a discarded material is recovered from the environment, and directly used as an ingredient) and, if comments are submitted that argue that such secondary materials (once recovered from the environment) should not be considered solid waste, the commenters should provide the basis or rationale for such a position (including a demonstration of how the secondary materials meet the legitimacy criteria outlined in section V.A.2) in order for the Agency to evaluate the arguments that are presented by the commenters. The Agency specifically requests comments on the extent to which secondary materials that have already been discarded (e.g., coal ash that has been landfilled) are later processed and used as ingredients in combustion units. Commenters should provide a description of the types of processing that the secondary material undergoes. EPA is also soliciting comment on the level of processing that would be considered sufficient to transform a discarded material into an ingredient product.

6. Hazardous Secondary Materials That May Be Excluded From the Definition of Solid Waste Under RCRA Subtitle C Because They Are More Like Commodities Than Wastes

Under the hazardous waste regulations, the Agency has evaluated a number of hazardous secondary materials that are recycled and determined that such materials, while they either met a listing description or exhibited one or more of the hazardous characteristics, were not "solid wastes"

for purposes of the Subtitle C hazardous waste regulations. Specifically, the following materials may be burned under certain conditions and are not solid wastes, but only for purposes of the hazardous waste regulations—black liquor, spent sulfuric acid, and comparable fuels. EPA is interested in extending this determination so that these materials are not considered solid wastes under RCRA Subtitle D.

The Agency believes that it has sufficient information in the rulemaking records that covered the determinations for black liquor, spent sulfuric acid,⁵⁷ and comparable fuels⁵⁸ to conclude that the exclusions are broadly applicable to the definition of solid waste; however, it solicits comment on whether it needs to develop additional information and provide new arguments. EPA emphasizes that it is not requesting comment on the solid waste definition for purposes of its hazardous waste regulation, but only on whether the exclusion conceptually applies to the definition of solid waste that is applicable to non-hazardous Subtitle D wastes, when these secondary materials are used as a fuel or ingredients.

EPA provides the following summaries of its regulations and solicits any views from the public on these materials. Specifically, a determination was made that black liquor reclaimed in a pulping liquor recovery furnace and then reused in the pulping process and spent sulfuric acid used to produce virgin sulfuric acid were not solid wastes under the hazardous waste regulations. The reason that these hazardous secondary materials were determined not to be solid wastes was because these hazardous secondary materials were determined to be an integral part of the manufacturing process. With respect to comparable fuels, EPA determined that certain hazardous secondary materials that meet specific requirements to ensure the material's toxic constituents and physical properties are similar to commercial (benchmark) fuels, are products, not solid wastes. See 63 FR 33781. The Agency has also recently finalized a rule that expands the Comparable Fuels Exclusion to encompass a new category of liquid hazardous secondary materials known as emission-comparable fuel (ECF).⁵⁹ By

expanding the Comparable Fuels Exclusion, ECF will be handled as a valuable commodity. ECF is subject to the same regulations that currently apply to the Comparable Fuels Exclusion, with the exception of certain oxygenates and hydrocarbons (constituents which contribute energy value to the fuel). The rule specifies conditions on burning ECF which assure that emissions from industrial boilers burning ECF are comparable to emissions from industrial boilers burning fuel oil.

The Agency specifically states in the hazardous waste rules that such “solid waste” determinations are only with respect to the Subtitle C hazardous waste regulations (see 40 CFR 261.1(b)(1)). EPA, however, wishes to obtain comment on whether to extend these exclusions beyond the hazardous waste regulations and apply them to these materials when they are used as a fuel or ingredient, and they meet the general principles discussed in today's notice.

VI. Additional Areas for Comment

The Agency is also interested in receiving comments on the following four issues.

A. Fuels or Materials That Have Been Discarded That Are Generally Considered To Be Solid Wastes

The Agency considers materials that have been previously discarded and not subsequently processed into a legitimate fuel or ingredient products as solid wastes under RCRA. However, the question has been raised by certain industry groups and states⁶⁰ as to whether these discarded materials—once recovered from the environment—may no longer be considered solid waste (assuming they are in fact valuable fuels or ingredients and otherwise meet the legitimacy criteria once recovered). Therefore, the Agency solicits comment on whether there are any circumstances under which these secondary materials should not be considered solid wastes under RCRA.

EPA recognizes that waste can be burned for energy or material recovery, and such materials, once they have been discarded, generally are considered “solid wastes” and units that burn these materials would be subject to the CAA section 129 incineration standards if

they have not been processed into a legitimate ingredient or fuel. However, as discussed in section III of this preamble, as prices for primary materials have increased, in many cases, the economics of using secondary materials as a substitute for primary materials has shifted, changing how the secondary materials are considered in commerce. In addition, new technologies can expand the universe of secondary materials that could be considered legitimate fuels.

The Agency is therefore interested in taking comment on the situation where discarded materials can be directly used as a legitimate fuel or ingredient (as defined in section V.A.2) without processing because they are indistinguishable in all relevant aspects from a fuel or ingredient product. (Note that the Agency is only requesting comment on these secondary materials at the point they have been removed from their “discard” environment and are being managed as a valuable commodity. Materials that have been disposed of in abandoned piles or landfills are clearly discarded while they remain in those environments and are subject to the appropriate federal, state and local regulations.) As an example, based on the results of EPA's 1997 study on “Air Emissions from Scrap Tire Combustion,” it was concluded that potential emissions from TDF are often less than, but at least generally within the same range as, emissions from conventional fossil fuels, as long as combustion occurs in a well-designed, operated, and well-maintained combustion device. Other data supports this conclusion. See background document titled “Materials Characterization Paper; Scrap Tires,” for a more detailed discussion on comparing TDF emissions to traditional fossil fuel emissions.

Coal refuse (i.e., mining rejects) is another secondary material that we believe falls within this category. Some of these materials were discarded by coal mining companies from the time mining first began in the Appalachians through the late 1970s. The materials had historically been piled through the Pennsylvania and West Virginia coal regions until laws were enacted in the late 1970s that required site reclamation. The advent of CFB combustion boilers, capable of efficiently burning fuels of lower calorific value, has resulted in the ability to use this material as a fuel (millions of tons of coal refuse have been burned as a fuel since the advent of CFBs). See background document titled “Materials Characterization Paper; Coal Refuse,” for more details.

⁵⁷ See Definition of Solid Waste Final Rule, January 4, 1985 at 50 FR 641–642, covering both black liquor and spent sulfuric acid.

⁵⁸ See “Expansion of the RCRA Comparable Fuels Exclusion (CFE)”, Final Rule, December 19, 2008, 73 FR 77953.

⁵⁹ See “Expansion of the RCRA Comparable Fuels Exclusion (CFE)”, Final Rule, December 19, 2008, 73 FR 77953.

⁶⁰ For example, see the Hybrid Regulatory Approach paper presented by the multi-industry coalition of stakeholders (PCA/CIBO/AF&PA/USWAG/RMA) in the docket established for this action entitled: “Outline of Regulatory Approach to Determine Materials Considered Fuels—not Solid Wastes—under RCRA,” June 12, 2008. We have had verbal discussions with the states on this issue as well.

The Agency specifically solicits comment on whether there are circumstances under which materials that have been discarded and which are legitimate fuels or ingredients should or should not be considered a solid waste once they are removed or recovered from the “discard” environment and managed as a legitimate fuel or ingredient.

B. Other Approaches for Determining Whether Secondary Materials Are Fuels and Not Solid Wastes

The Agency is also interested in receiving comments on an approach, as presented to the Agency by industry representatives, for determining when secondary materials are fuels and thus, not solid waste, and how the process may be implemented.⁶¹ Many aspects of the approach presented have been discussed throughout this ANPRM, with the common principle that certain secondary materials are not solid waste when burned for energy if they meet established criteria or are specifically identified not to be solid waste. For example, industry representatives suggest that material should be evaluated, on a case-by-case basis, to identify which criteria have been satisfied and determine whether the material is legitimately handled as a fuel. Criteria identified by industry stakeholders may include: Handling and storage of materials to minimize loss, use of materials within a reasonable period of time, material value (e.g., whether there is a market for the material as a fuel, internal or external to the company), material managed and treated as a commodity, and processing of material to enhance fuel value. Industry stakeholders also recommend that EPA should list by regulation specific materials as fuels, rather than solid wastes. Thus, under the industry recommended approach, it would not be necessary to evaluate whether the criteria have been satisfied in every instance. Specifically, listed materials that were recommended include: Traditional/historical fuels (e.g., coal, fuel oil, pet coke, coal refuse, used oil regulated under 40 CFR Part 279, synfuel, TDF, biomass fuel, biofuel, and gas pipeline condensate), materials specifically excluded from RCRA Subtitle C that have beneficial fuel value, materials combusted for chemical recovery, materials that are modified or

processed to produce a product of significant fuel or feedstock value, biomass materials from agricultural and forest resources, tires reclaimed via state programs, materials that had been discarded, but can be processed for use as a fuel or feedstock, and materials that a state approves as a fuel or determines can be beneficially reused.

To implement the aforementioned concepts for determining when or which secondary materials are fuels, industry presented two methods, which were not meant to be mutually exclusive. One method implements the criteria concept, by which an owner or operator of a combustion device must determine that the material meets the criteria set forth and maintain records to demonstrate that these criteria are met. (Presumably, the owner or operator would be subject to potential enforcement action if EPA determined that the criteria were misapplied.) The other method implements an extension of the listed materials concept by allowing an owner or operator to petition EPA or the state to specifically list a material (in addition to a pre-established list of materials). In a petition, the owner or operator would use the criteria as the basis for proposing that EPA or the state list the material (although industry notes that not all criteria need to be satisfied to qualify as a fuel), or the owner or operator could submit additional information to demonstrate the environmental equivalence of the material to other listed fuels.

The Agency solicits comments on whether the rules should include a petition process that would allow a person to submit a rulemaking petition and argue, on a case-by-case basis, that a secondary material is not a solid waste. This petition process would address situations where a material would otherwise be considered a solid waste under current regulations. As discussed in section V.A.6, the Agency has excluded certain materials from being a solid waste under the Subtitle C hazardous waste regulations. Should the Agency allow persons to petition the Agency to have a secondary material excluded from the definition of solid waste based on the legitimacy criteria discussed in section V.A.2? The Agency is interested in receiving comments on the validity and potential specific procedures of a case-by-case petition process by the owner or operator of a combustion device, including what criteria should be considered in evaluating such petitions. In addition, we also request comment on the concept of establishing a list of materials that are fuels.

For more information, see the multi-industry coalition’s paper in the docket established for this action entitled: “Outline of Regulatory Approach to Determine Materials Considered Fuels—not Solid Wastes—under RCRA,” June 12, 2008. The Agency also has received several papers from industry groups which we have reviewed and considered in drafting this ANPRM that are also available for viewing and comment in the docket.

*C. Materials for Which State Beneficial Use Determinations Have Been Made*⁶²

States regulate the management of non-hazardous solid waste, typically including secondary industrial materials, but many have a process or promulgated regulations to determine when these materials are no longer wastes, because they can beneficially and safely be used as products in commerce. The Agency is also soliciting comments on state beneficial use determinations and how those determinations deal with solid wastes, and how those decisions should be considered by EPA in determining what is or is not a solid waste under RCRA, which in turn determines how it is regulated under the CAA standards. Many state determinations addressing a material’s beneficial use and solid waste status are consistent with the principles explained in this ANPRM, but some state determinations (as previously discussed, both wastes and non-wastes may be used beneficially) may be inconsistent. In order for state programs to qualify materials as not solid waste under federal law, under the terms suggested in this notice, secondary materials would need to be legitimate fuels or ingredients and otherwise meet the conditions of the federal regulations.

As we have noted previously, states are the lead Agencies for implementing the non-hazardous waste programs and, as such, we want to make sure that state programs are not adversely affected by any decisions that are made by EPA. We see a benefit to deferring to state decisions, which are able to consider site specific information. The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) reports that they receive requests from the regulated community to consider non-hazardous, industrial secondary materials as not being solid wastes when they are beneficially used. Most states (30 of 34 reporting) indicated they had either formal or

⁶¹ See the Hybrid Regulatory Approach paper presented by the multi-industry coalition of stakeholders (PCA/CIBO/AF&PA/USWAG/RMA) in the docket established for this action entitled: “Outline of Regulatory Approach to Determine Materials Considered Fuels—not Solid Wastes—under RCRA,” June 12, 2008.

⁶² This applies to state beneficial use determinations for secondary materials used as fuels or ingredients in combustion units that are not determined to be “non-wastes” pursuant to this rulemaking effort.

informal decision-making processes or beneficial use programs relating to the use of solid wastes. Materials are no longer subject to the state's solid waste regulations under the state rules when a state determines that the secondary materials are no longer solid wastes when beneficially used.

The Agency acknowledges state beneficial use determinations and seeks comment on whether to consider secondary materials that receive a state beneficial use determination for use as a fuel or as an ingredient as not a solid waste, should also not be considered a solid waste under federal law. Commenters who support such a position should provide the basis or rationale for this position. For example, would a determination be needed that shows the beneficial use determination was in-line with EPA's principles as outlined in section V.A.2. (i.e., whether they were legitimate fuels or ingredients)?

D. Biofuels

Biofuels and byproducts from the production of biofuels are non-traditional alternative fuels being offered for stakeholder consideration. Biofuels can be generally described as a gas or liquid fuel made from biological materials, including plants, animal manure, and other organic sources. Thus, biofuels produced from these materials, such as ethanol and biodiesel are not considered to be solid wastes themselves, but rather are viewed as legitimate fuel products. Biofuels production has increased dramatically in the past few years and is expected to continue increasing over the coming years. The Energy Policy Act of 2005 amended the CAA to establish a Renewable Fuel Standard (RFS) program which established a major new federal renewable fuel volume mandate. While market forces initially caused renewable fuel use to far exceed these mandates, this program provided certainty that at least a minimum amount of renewable fuel would be used in the U.S. transportation market, which in turn provided assurance for investment in production capacity. The Energy Independence and Security Act of 2007 (EISA) updated the RFS program to include a new definition of renewable fuels that accounted for the fuel life-cycle emissions of greenhouse gases (GHG)⁶³ and also increased the

⁶³ A "renewable fuel" is defined in EISA as a fuel that is produced from renewable biomass and that is used to replace or reduce the quantity of fossil fuel present in transportation fuel. "Renewable biomass" is defined as (1) Planted crops and crop residue, (2) planted trees and tree residue, (3) animal waste material and animal byproducts, (4)

total renewable fuel volume mandate to 36 billion gallons per year by 2022; the statute also established four specific categories of renewable fuels, each with a separate volume mandate. These categories are renewable fuel, advanced biofuel, biomass-based diesel, and cellulosic biofuel.

Biofuels production can be viewed as including both the feedstock materials that are used to produce biofuels, as well as the byproducts generated from the production of biofuels. EPA considers these materials to be legitimate alternative fuels when they have meaningful heating value, do not contain contaminants that are significantly higher in concentration than traditional fuels, and are handled as a valuable commodity. For example, a project completed by the University of Georgia (UGA) Engineering Outreach Service (EOS) demonstrated that biofuels processed from fats and grease (chicken fat, yellow grease, choice white grease, and beef tallow), either singly or blended with No. 2 fuel oil, are technically and economically viable alternatives to No. 2 fuel oil in industrial boilers.⁶⁴ We request additional data and comment on the extent to which fats, oils, and greases (FOGs) and related biomass materials that can be used as feedstocks to produce biofuels and that are not previously addressed in this ANPRM, are also used directly as fuels in stationary combustion sources. Further, the Agency requests comment on the extent to which FOGs and biomass materials are processed into biofuels for use in stationary combustion sources, such that their assessment as part of this rulemaking effort is warranted. For example, the U.S. Energy Information Administration estimated used cooking oil is produced at a rate of some 100 million gallons per day in the USA.⁶⁵ Literature suggests that biodiesel can be prepared from waste cooking oil. Although there are instances where such oil is used as a fuel for engines with only minimal processing (such as filtering), more intensive processing (such as the addition of ethyl alcohol with sodium hydroxide as a catalyst for the transesterification of vegetable oils and animal fats) is necessary to produce

slash and commercial thinnings, (5) biomass from the immediate vicinity of buildings, (6) algae, and (7) separated yard waste or food waste, including recycled cooking and trap grease.

⁶⁴ FY 2005 *FoodPAC* Final Report; "Combustion of Poultry Fat for Plant Heat and Steam," University of Georgia.

⁶⁵ Radich, A. Biodiesel performance, costs, and use. U.S. Energy Information Administration, 2006. <http://www.eia.doe.gov/oiaf/analysispaper/biodiesel/index.html>.

true biodiesel fuel.⁶⁶ Finally, we request comment on whether non-hazardous byproducts generated from the production of biofuels, such as dry distiller's grain from corn ethanol and lignin from cellulosic ethanol, are being used as alternative fuels, which therefore should be assessed as part of this rulemaking effort.

VII. Statutory and Executive Order Reviews

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action." 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.

Generally, because this action is "advanced" in nature and does not, therefore, propose any requirements on any entities, the various administrative requirements EPA must address in the rulemaking process are not applicable. When EPA issues a notice of proposed rulemaking, EPA will address those requirements. EPA expects to prepare an Economic Assessment (EA) in support of the proposed action. We will submit this EA, along with the proposed rulemaking to OMB for review.

List of Subjects in 40 CFR Part 257

Environmental protection, Waste treatment and disposal.

Dated: December 22, 2008.

Stephen L. Johnson,

Administrator.

[FR Doc. E8-30987 Filed 12-31-08; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[MB Docket No. 08-253; FCC 08-278]

Replacement Digital Television Translator Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes and seeks comment on rules that would create a new "replacement" digital television translator service. The new replacement

⁶⁶ *Energies* 2008, 1, 3-18; DOI: 10.3390/en1010003, "Waste Cooking Oil as an Alternate Feedstock for Biodiesel," <http://www.mdpi.com/1996-1073/1/1/3/pdf>.

digital television translator service will permit full-service television stations to continue to provide service to viewers within their coverage area who have lost service as a result of those stations' digital transition. We seek comment on how to implement this new service and tentatively conclude that it should be subject to all other rules for television translators with respect to secondary frequency use, filing and processing of applications, construction, and operation. Finally, we announce interim filing procedures to begin acceptance of applications for replacement translators and the authorization of temporary facilities.

DATES: Comments for this proceeding are due on or before January 12, 2009; reply comments are due on or before January 22, 2009.

ADDRESSES: You may submit comments, identified by MB Docket No. 08–253 and/or FCC 08–278, 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.

■ **Mail:** 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.

■ **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: Shaun Maher, Shan.Maher@fcc.gov of the Media Bureau, Video Division, (202) 418–1600. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, send an e-mail to PRA@fcc.gov or contact Cathy Williams at (202) 418–2918, or via e-mail at Cathy.Williams@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking*, FCC 08–278,

adopted on December 22, 2008, and released on December 23, 2009. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC 20554. It may also be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554; the contractor's Web site: <http://www.bcpweb.com>; or by calling (800) 378–3160, facsimile (202) 488–5563, or e-mail FCC@BCPIWEB.com. These documents 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.) Additionally, the complete item is available on the Federal Communications Web site at <http://www.fcc.gov>. 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).

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page 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).

Initial Paperwork Reduction Act of 1995 Analysis

This Notice of Proposed Rulemaking was analyzed with respect to the Paperwork Reduction Act of 1995 ("PRA")¹ and will revise an existing information collection.² The Commission will seek approval under the PRA under OMB's emergency processing rules³ for this information collection requirement in order to

¹ The Paperwork Reduction Act of 1995 ("PRA"), Public Law 104–13, 109 Stat 163 (1995) (codified in Chapter 25 of Title 44 U.S.C.).

² The existing information collection that will be revised to add the new proposed information collection requirement is OMB control number 3060–1086. The new proposed information collection requirement is contained in 47 CFR 74.787(a)(1)(5).

³ See 5 CFR 1320.13.

implement the rules and policies for a new replacement digital low power television (LPTV) translator service that would permit full-service television stations to continue to provide service to viewers within their coverage area who have lost service as a result of those stations' digital transition. We believe there is good cause for requesting emergency PRA approval from OMB due to the statutory digital television transition deadline of February 17, 2009.⁴

Synopsis

Creation of New Replacement Digital Television Translator Service

We tentatively conclude that replacement translators should be licensed only for digital operation and should be licensed only on channels 2–59 and not for out-of-core channels 60–69. In order to prevent possible interference to public safety entities, and avoid the potential for displacement of replacement translator facilities, we believe that replacement translators should not be licensed on channels 60–69. We tentatively conclude that stations seeking a replacement translator on channels 52–59 be required to certify in their applications the unavailability of any suitable in-core channel for this purpose. We propose defining “suitable in-core channel” as one that would enable the station to produce a digital service area comparable to its analog service area. This is similar to the requirement we adopted for stations proposing a digital companion channel on channels 52–59.⁵ We further propose requiring stations seeking replacement translators on channels 52–59 to provide the notifications to wireless licensees that we adopted for low power television and TV translator stations seeking to flash cut or a digital companion channel on channels 52–59.⁶ We seek comment on these proposals.

⁴ Due to the short time frame provided for the Commission to act on the new replacement digital low power television translator service, we requested and received OMB approval to waive **Federal Register** notice for this emergency request under the PRA. See 5 CFR 1320.13(d).

⁵ See Amendment of Parts 73 and 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, 19 FCC Rcd 19331, 71 (2004).

⁶ *Id.* Low power television and TV translator station digital flash cut and digital companion channel applicants on channels 52–59 are required to notify all potentially affected 700 MHz commercial wireless licensees of the spectrum comprising the proposed TV channel and the spectrum in the first adjacent channels thereto. They are also required to provide notification to co-channel and first adjacent channel licensees whose

We further tentatively conclude that applications for replacement translators should be given licensing priority over all other low power television and TV translator applications except displacement applications (for which they would have co-equal priority). Therefore, a replacement translator application, when filed, would have processing priority over other applications for new stations, major changes and minor changes. Furthermore, we tentatively conclude that we should limit the eligibility for such service to only those full-service television stations that can demonstrate that a portion of their analog service area⁷ will not be served by their full, post-transition digital facilities and for translators to be used for that purpose. We seek comment on these tentative conclusions.

In *Unlicensed Operation in the TV Broadcast Bands*, we adopted rules to allow unlicensed radio transmitters to operate in the broadcast television spectrum at locations where that spectrum is not being used by licensed services (this unused TV spectrum is often termed “white spaces”).⁸ Unlicensed devices must fully protect the licensed services, such as television translators, that operate in the TV bands. We seek to comment on the effect, if any, of this new translator service on the prospects for future white spaces use of the spectrum.

We further tentatively conclude that the service area of the replacement translator should be limited to only a demonstrated loss area and seek comment on whether a replacement translator should be permitted to expand nominally a full-service station's post-transition, digital service area in order to fully cover the loss area. We recognize that it may be impossible for some full-service stations to site a translator that replaces a loss area without also slightly expanding the

geographic service area boundaries lie within 75 miles and 50 miles, respectively, of the proposed digital LPTV or TV translator station location. A station seeking an on-channel digital conversion must provide such written notification at least 30 days in advance of filing its minor change application. An applicant for a digital companion channel must provide the required notifications within 30 days of submitting its “long-form” application. In both cases, applicants must certify in their applications that the notification requirements have been met.

⁷ We define “analog service area” as the authorized service area actually served by the analog signal prior to analog termination for the transition, consistent with our approach in the DTS proceeding. See *DTS Report and Order* at 28.

⁸ See *Unlicensed Operation in the TV Broadcast Bands*, ET Docket No. 04–186, *Second Report and Order and Memorandum Opinion and Order*, FCC 08–260, November 14, 2008 (*Unlicensed Operation in the TV Broadcast Bands*).

station's digital service area. Although we seek to limit these new translators to replacing service in a loss area, and not to expanding service, we tentatively conclude that we should allow *de minimis* expansion of service and seek comment on how to define the term “*de minimis*” in this context.

We tentatively conclude that replacement digital television translator stations should be licensed with “secondary” frequency use status. These stations would not be permitted to cause interference to, and must accept interference from, full-service television stations, certain land mobile radio operations and other primary services.⁹

Licensing of Replacement Digital Television Translator Stations

We tentatively conclude that, unlike other television translator licenses, the license for the replacement translator will be associated with the full power station's main license.¹⁰ Therefore, the replacement translator license could not be separately assigned or transferred and would be renewed or assigned along with the full-service station's main license. We believe that such a measure is necessary to ensure that the replacement translator service is limited to only those situations where a station seeks to restore service to a loss area and is used for that purpose.

We tentatively conclude that the other rules associated with television translator stations would apply to the new replacement translator service, including those rules concerning the filing of applications,¹¹ payment of filing fees,¹² processing of applications,¹³ power limits,¹⁴ out-of-channel emission limits,¹⁵ call signs,¹⁶ unattended operation,¹⁷ and time of operation.¹⁸ We tentatively conclude that stations seeking a replacement digital television translator would submit a completed FCC Form 346 and pay the requisite \$675.00 filing fee for a new station. The Commission would process such applications, and those found acceptable would be placed on a “proposed grant” public notice subject to petitions to deny. New stations would receive a call sign assigned to digital translator stations (e.g., K20AA–D). Although we expect full-service stations

⁹ See, e.g., 47 CFR 74.703, 74.709, 90.303.

¹⁰ See 47 CFR 73.3540(e).

¹¹ See 47 CFR 73.3572(a)(2).

¹² See 47 CFR 1.1102.

¹³ See 47 CFR 73.3572(a). Cite rule on processing of translator applications.

¹⁴ See 47 CFR 74.735.

¹⁵ See 47 CFR 74.736.

¹⁶ See 47 CFR 74.791.

¹⁷ See 47 CFR 74.734.

¹⁸ See 47 CFR 74.763.

to quickly construct their replacement translator facilities, we seek comment on whether to limit the construction period for replacement translators to six months. Although TV translators are ordinarily afforded a three-year period for completion of construction,¹⁹ we believe that expedited construction of replacement translators is vital to the continued provision of television service following the digital transition and that a shorter construction period is warranted.

Interim Filing Procedures

In order to preserve service to possible loss areas and expedite the future consideration of applications for replacement translator facilities, we will begin accepting applications for replacement digital television translator stations following the release date of this Notice of Proposed Rulemaking. We will withhold the processing of such applications pending the outcome of this proceeding.²⁰ In the interim full-service stations will be permitted to submit requests for special temporary authority (STA) pursuant to our existing STA procedures in order to operate temporary replacement translator facilities during the pendency of this proceeding. Applications will be filed on a first-come, first-serve basis.²¹ If we adopt our proposal to create this new service, and provide with them a processing priority, the processing of applications for replacement translators will be completed and mutually exclusive applications will be resolved by our broadcast competitive bidding rules.²² We propose to allow a 10-day opportunity for mutually exclusive replacement translator applicants to settle or otherwise find an engineering solution to resolve their mutual exclusivity. We propose that this will expedite the final processing of such applications and ensure that stations are able to replace service to loss areas as quickly as possible.

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended ("RFA")²³ the Commission has

¹⁹ See 47 CFR 73.3598.

²⁰ We delegate to the Media Bureau authority to announce the exact date that applications for replacement translator stations will begin to be accepted and the interim procedures and policies that will be applied to such filings.

²¹ Any applications filed on or before the effective date of any rules adopted in this proceeding will be treated as if they were filed the day after the effective date.

²² See 47 CFR 73.5000 *et seq.*

²³ See 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601 *et seq.*, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996

prepared this present Initial Regulatory Flexibility Analysis ("IRFA") concerning the possible significant economic impact on small entities by the policies and rules proposed in this *Notice of Proposed Rulemaking* (NPRM). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments indicated on the first page of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).²⁴ In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.²⁵

Need for and Objectives of the Proposed Rules

Full-service television stations have been undertaking changes to their final, post-transition digital facilities in order to continue to provide the high level of service to their community of license after the completion of the digital transition. In some cases, a portion of the existing analog service areas of some full-service stations will no longer be able to receive service after the station transitions to digital broadcasting. Some of these "loss" areas are a result of unavoidable engineering changes that stations were required to implement in order to avoid interference or other problems on their post-transition digital channel. At times, the analog signal of certain full-service stations could not be replicated because of technical complexities. To assist full-service stations to replace service to these loss areas, this NPRM proposes to establish a new "replacement" digital television translator service that would permit full-service television stations to obtain new digital translators to maintain existing service and request comment on an expedited basis.

The NPRM tentatively concludes that replacement translators should be licensed only for digital operation and should be licensed on only channels 2–59 and not for out-of-core channels 60–69. The NPRM tentatively concludes that stations seeking a replacement translator on channels 52–59 be required to certify in their applications the unavailability of any suitable in-core channel for this purpose.

The NPRM further tentatively concludes that applications for replacement translators should be given licensing priority over all other low

("SBREFA"), Public Law 104–121, Title II, 110 Stat. 847 (1996).

²⁴ See 5 U.S.C. 603(a).

²⁵ See *id.* 603(a).

power television and TV translator applications except displacement applications (for which they would have co-equal priority). The NPRM also tentatively concludes that the Commission should limit the eligibility for such service to only those full-service television stations that can demonstrate that a portion of their analog service area will not be served by their full, post-transition digital facilities and for translators to be used for that purpose. The NPRM further tentatively concludes that the service area of the replacement translator should be limited to only a demonstrated loss area and seeks comment on whether a replacement translator should be permitted to expand slightly a full-service station's post-transition, digital service area. Finally, the NPRM tentatively concludes that replacement digital television translator stations should be licensed with "secondary" frequency use status.

The NPRM tentatively concludes that, unlike other television translator licenses, the license for the replacement translator should be associated with the full power station's main license. Therefore, the replacement translator license could not be separately assigned or transferred and would be renewed or assigned along with the full-service station's main license. The NPRM also tentatively concludes that the other rules associated with television translator stations would apply to the new replacement translator service including those rules concerning the filing of applications, payment of filing fees, processing of applications, power limits, out-of-channel emission limits, call signs, unattended operation, and time of operation. The NPRM seeks comment whether to limit the construction period for replacement translators to six months.

In order to preserve service to possible loss areas, and expedite the future consideration of applications for replacement translator facilities, the NPRM announces that the Commission will begin accepting applications for replacement digital television translator stations following the release date of the NPRM. The Commission will withhold the processing of such applications pending the outcome of the rulemaking proceeding. In the interim, full-service stations will be permitted to submit requests for special temporary authority (STA) in order to operate temporary replacement translator facilities during the pendency of this proceeding. The NPRM delegates to the Media Bureau authority to announce the exact date that applications for replacement translator stations will begin to be

accepted and the interim procedures and policies that will be applied to such filings. Applications will be filed on a first-come, first-serve basis.

Legal Basis

The authority for the action proposed in this rulemaking is contained in Sections 1, 4(i) and (j), 7, 301, 302, 303, 307, 308, 309, 312, 316, 318, 319, 324, 325, 336, 337, 614 and 615 of the Communications Act of 1934, 47 U.S.C. 151, 154(i) and (j), 157, 301, 302a, 303, 307, 308, 309, 312, 316, 318, 319, 324, 325, 336, 337, 534, and 535.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules, if adopted.²⁶ The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small government jurisdiction."²⁷ In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.²⁸ A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.²⁹

Television Broadcasting. The SBA defines a television broadcasting station as a small business if such station has no more than \$14 million in annual receipts.³⁰ Business concerns included in this industry are those "primarily engaged in broadcasting images together with sound."³¹ According to

Commission staff review of the BIA Publications, Inc. Master Access Television Analyzer Database (BIA) on March 30, 2007, about 986 of an estimated 1,374 commercial television stations³² (or approximately 72 percent) have revenues of \$13.5 million or less and thus qualify as small entities under the SBA definition. We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations³³ must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. The Commission has estimated the number of licensed NCE television stations to be 380.³⁴ The Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

Class A TV, LPTV, and TV Translator Stations. The same SBA definition that applies to television broadcast licensees would apply to these stations. The SBA defines a television broadcast station as a small business if such station has no more than \$14 million in annual receipts.³⁵

Currently, there are approximately 567 licensed Class A stations, 2,227 licensed LPTV stations, 4,518 licensed TV translators and 11 TV booster stations.³⁶ Given the nature of these services, we will presume that all of these licensees qualify as small entities under the SBA definition. We note, however, that under the SBA's

programs to the public on a predetermined schedule. Programming may originate in their own studios, from an affiliated network, or from external sources." Separate census categories pertain to businesses primarily engaged in producing programming. See Motion Picture and Video Production, NAICS code 512110; Motion Picture and Video Distribution, NAICS Code 512120; Teleproduction and Other Post-Production Services, NAICS Code 512191; and Other Motion Picture and Video Industries, NAICS Code 512199.

³² Although we are using BIA's estimate for purposes of this revenue comparison, the Commission has estimated the number of licensed commercial television stations to be 1374. See News Release, "Broadcast Station Totals as of December 31, 2006" (dated Jan. 26, 2007); see <http://www.fcc.gov/mb/audio/totals/bt061231.html>.

³³ "[Business concerns] are affiliates of each other when one concern controls or has the power to control the other or a third party or parties controls or has to power to control both." 13 CFR 121.103(a)(1).

³⁴ Broadcast Stations Total as of December 31, 2006.

³⁵ See 13 CFR 121.201, NAICS Code 515120.

³⁶ See News Release, "Broadcast Station Totals as of December 31, 2006" (dated Jan. 26, 2007); <http://www.fcc.gov/mb/audio/totals/bt061231.html>.

definition, revenue of affiliates that are not LPTV stations should be aggregated with the LPTV station revenues in determining whether a concern is small. Our estimate may thus overstate the number of small entities since the revenue figure on which it is based does not include or aggregate revenues from non-LPTV affiliated companies. We do not have data on revenues of TV translator or TV booster stations, but virtually all of these entities are also likely to have revenues of less than \$13 million and thus may be categorized as small, except to the extent that revenues of affiliated non-translator or booster entities should be considered.

In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore over-inclusive to that extent. Also as noted, an additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

The NPRM proposes one new reporting requirement. The NPRM proposes that full-service stations seeking a new replacement digital television translator station submit a showing with their FCC Form 346 that they have a loss area as a result of their transition to digital and that the proposed replacement translator will serve the loss area. The new reporting requirement will not differently affect small entities.

Steps Taken To Minimize Significant Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification,

²⁶ *Id.* at 603(b)(3).

²⁷ 5 U.S.C. 601(6).

²⁸ *Id.* Section 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**." 5 U.S.C. 601(3).

²⁹ 15 U.S.C. 632. Application of the statutory criteria of dominance in its field of operation and independence are sometimes difficult to apply in the context of broadcast television. Accordingly, the Commission's statistical account of television stations may be over-inclusive.

³⁰ See 13 CFR 121.201, NAICS Code 515120 (adopted Oct. 2002).

³¹ NAICS Code 515120. This category description continues, "These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the

consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.³⁷

The Commission is aware that some full service television stations operate with limited budgets. Accordingly, every effort was taken to propose rules that impose the least possible burden on all licensees, including smaller licensed entities. Existing rules, forms and procedures will be used to implement this new service thereby reducing the burden on small entities.

The NPRM tentatively concludes that replacement translators should be licensed only for digital operation and should be licensed on only channels 2–59 and not for out-of-core channels 60–69. Alternatively, the Commission could have allowed stations to file for analog facilities but the digital transition for full power stations is closely approaching thus making the need for further analog service unnecessary. Further, the Commission could have allowed for replacement translators to be filed on channels 60–69, but it is likely that these stations would very quickly be displaced by wireless and public safety entities and small entities would waste their resources and time having to find a new channel for their proposed facility. The NPRM tentatively concludes that stations seeking a replacement translator on channels 52–59 be required to certify in their applications the unavailability of any suitable in-core channel for this purpose. The alternative approach would be to not require a certification, but that could lead to administrative delay and a waste of administrative resources as the staff would have to verify the lack of channels.

The NPRM further tentatively concludes that applications for replacement translators should be given licensing priority over all other low power television and TV translator applications except displacement applications (for which they would have co-equal priority). The Commission could have proposed allowing no such priority, but this alternative was not considered because it would result in many more mutually exclusive filings and delay the implementation of this valuable service. The NPRM also tentatively concludes that the Commission should limit the eligibility for such service to only those full-service television stations that can demonstrate that a portion of their

analog service area will not be served by their full, post-transition digital facilities and for translators to be used for that purpose. Alternatively, the Commission could have allowed all interested parties to file for new translators, however such approach was not considered because it would also result in numerous mutually exclusive filings and would greatly delay implementation of this needed service. The NPRM further tentatively concludes that the service area of the replacement translator should be limited to only a demonstrated loss area and seeks comment on whether a replacement translator should be permitted to expand slightly a full-service station's post-transition, digital service area. Once again, the Commission could have allowed stations to file for expansion of their existing service areas but such an alternative was not seriously considered because it could result in the use of valuable spectrum that the Commission seeks to preserve for other uses such as new digital low power service. Finally, the NPRM tentatively concludes that replacement digital television translator stations should be licensed with "secondary" frequency use status. The Commission could have proposed that replacement translators be licensed on a primary frequency use basis, but this alternative was not proposed because it would result in numerous interference and licensing problems and could disrupt the full-power digital transition.

The NPRM tentatively concludes that, unlike other television translator licenses, the license for the replacement translator should be associated with the full power station's main license. Therefore, the replacement translator license could not be separately assigned or transferred and would be renewed or assigned along with the full-service station's main license. Alternatively, the Commission could have proposed that the replacement translator license be separate from the main station's license, however this approach was not seriously considered because it could result in licenses being sold or modified to serve areas outside of the loss area, would undermine the purpose of this new service. The NPRM also tentatively concludes that the other rules associated with television translator stations would apply to the new replacement translator service including those rules concerning the filing of applications, payment of filing fees, processing of applications, power limits, out-of-channel emission limits, call signs, unattended operation, and time of operation. The alternative could have been to design all new rules for this service, but that alternative was

not considered as it would adversely impact stations' ability to quickly implement these new translators. The NPRM seeks comment whether to limit the construction period for replacement translators to six months. Alternatively, the Commission could have proposed that the existing three-year construction period be allowed, however that alternative was not proposed in an effort to ensure that replacement translators are built and operating quickly to replace loss areas.

Federal Rules Which Duplicate, Overlap, or Conflict With the Commission's Proposals

None.

The Commission will send a copy of the Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 74

Television, Television broadcasting, Low power television.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 74 as follows:

PART 74—EXPERIMENTAL RADIO AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

1. The authority for part 74 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 307, 336(f), 336(h) and 554.

§ 74.787 [Amended]

2. Section 73.787 is amended by adding paragraph (a)(5) to read as follows:

§ 74.787 Digital licensing.

(a) * * *

(5) *Application for replacement digital television translator.*

(i) An application for replacement digital television translator may be filed by a full-service television station that can demonstrate that a portion of its analog service area will not be served by its full, post-transition digital facilities. Replacement digital television translator may operate on channels 2–59. Applications for replacement digital television translator shall be given licensing priority over all other low power television and TV translator applications except displacement applications (for which they shall have

³⁷ 5 U.S.C. 603(c)(1)–(c)(4).

co-equal priority). The service area of the replacement translator shall be limited to only a demonstrated loss area. The license for the replacement digital television translator will be associated with the full power station's main license and may not be separately assigned or transferred and will be renewed with the full-service station's main license.

(ii) Each original construction permit for the construction of a replacement digital television translator station shall specify a period of six months from the date of issuance of the original construction permit within which construction shall be completed and application for license filed. The provisions of § 74.788(c) shall apply for stations seeking additional time to complete construction of their replacement digital television translator station.

(iii) A public notice will specify the date upon which interested parties may begin to file applications for replacement digital television translators. Such applications shall be filed on FCC Form 346, shall be subject to the appropriate application fee and shall be accepted on a first-come, first-serve basis. Mutually exclusive applications shall be resolved via the Commission's part 1 and broadcast competitive bidding rules, § 1.2100 *et seq.* and § 73.5000 *et seq.* of this chapter.

* * * * *

[FR Doc. E8-31227 Filed 12-29-08; 4:15 pm]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[Docket No. 0812121592-81605-01]

RIN 0648-AX40

Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery; Control Date for American Lobster

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

ACTION: Advance notice of proposed rulemaking; Consideration of a control date for the American lobster fishery.

SUMMARY: NMFS announces that it is considering, and is seeking public comment on a proposed rulemaking that would limit or restrict future access to

the American lobster (*Homarus americanus*) trap fishery in the Federal waters of Lobster Management Area 1 (Area 1), the inshore Gulf of Maine, based upon a permit holder's ability to document a history of fishing with lobster traps in Area 1 prior to the date of this notice. This notice should discourage American lobster non-trap vessels from entering the lobster trap fishery, and discourage American lobster trap vessels fishing in other lobster management areas from entering the Area 1 lobster trap fishery, based upon economic speculation while NMFS, in consultation with the Atlantic States Marine Fisheries Commission (Commission), considers whether and how access and effort should be controlled. This document, therefore, gives the public two-fold notification: first, that interested participants should locate and preserve records that substantiate and verify their past participation in the American lobster trap fishery in Federal waters; and second, that new participants to the Area 1 lobster trap fishery may be restricted from fishing in Area 1 with traps in the future depending upon the limited access criteria developed if, in fact, NMFS proceeds forward in this rulemaking.

DATES: Comments must be received no later than 5 p.m. eastern standard time on or before February 2, 2009.

ADDRESSES: You may submit comments, identified by RIN number 0648-AX40, by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking portal <http://www.regulations.gov>.
- Fax: (978) 281-9117, Attn: Bob Ross.
- Mail: Harold Mears, Director, State, Federal and Constituent Programs Office, Northeast Regional Office, NMFS, 55 Great Republic Drive, Gloucester, MA 01930-2276. Mark the outside of the envelope: "Comments on Lobster Control Date."

Instructions: All comments received are part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted via Microsoft Word, Microsoft Excel,

WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Bob Ross, Supervisory Fishery Management Specialist, 978-281-9234.

SUPPLEMENTARY INFORMATION: The American lobster fishery in the United States takes place from North Carolina to Maine. Over three-quarters of all American lobsters are landed in Maine, with most of the other landings occurring in or from Massachusetts, Rhode Island, Long Island Sound, and Georges Bank. The majority of American lobsters are taken in state waters, which extend from the coast to 3 nautical miles (5.56 kilometers) from shore. The offshore trap fishery, which occurs primarily in the offshore canyon areas at the edge of the continental shelf, has developed in the past 25 years and accounts for most of the remaining landings. The American lobster fishery is a year-round fishery in the United States, including the summer and fall months when the lobsters are molting. Approximately 96 percent of lobsters are taken in lobster traps. The rest are taken in trawls, gillnets, dredges, and by divers.

The Commission develops fishery conservation and management strategies for certain coastal species and coordinates the efforts of the states and Federal Government toward concerted sustainable ends. The Commission, under the provisions of the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act), decides upon a management strategy and then forwards that strategy to the states and Federal Government, along with a recommendation that the states and Federal Government take action (e.g., enact regulations) in furtherance of this strategy. The Federal Government is obligated by statute to support the Commission's American Lobster Interstate Fishery Management Plan (ISFMP) and overall fishery management efforts. At its October 2008 Annual Meeting, the Commission voted to initiate an addendum to the ISFMP that includes options for a limited entry program for Area 1. In the same motion, the Commission voted to request the Secretary of Commerce publish a control date in the **Federal Register** that may be used to limit future participation in the Area 1 Federal American lobster trap fishery to those Federal permit holders who could document trap fishing history prior to the control date. The control date is the publication date of this advance notice of proposed rulemaking in the **Federal Register**.

There has been a dramatic increase in fishing effort since the 1970s and effort

continues at historically high levels. NMFS estimates that each American lobster trap remains in the water about 30 percent longer than in 1970 before being hauled. Current fishing effort removes a large proportion of lobsters before they have had a chance to spawn even once, and the average size of lobsters landed continues to drop. The most recent peer-reviewed lobster stock assessment, completed in 2005, showed that the American lobster resource presents a mixed picture (see the Commission Stock Assessment Report No. 06-03, published January 2006 at www.asmf.org). One theme throughout the assessment was the high fishing effort and high mortality rates in all three stock areas. The assessment indicated that there is stable abundance for the Georges Bank (GBK) stock and much of the Gulf of Maine (GOM) stock and decreased abundance and recruitment, yet continued high fishing mortality rates, for the Southern New England (SNE) stock and in Statistical Area 514 (Massachusetts Bay and Stellwagen Bank) in the GOM stock. Of particular concern in the 2005 stock assessment report is the SNE stock, where depleted stock abundance and recruitment coupled with high fishing mortality rates over the past few years led the stock assessment and peer review panel to recommend additional harvest restrictions. The SNE stock encompasses all of Areas 4, 5, and 6, and part of Areas 2 and 3. Overall, stock abundance in the GOM is relatively high with recent fishing mortality comparable to the past. The GOM stock encompasses all of Area 1, and part of both Area 3 and the Outer Cape Management Area. Currently, high lobster fishing effort levels in GOM continue in concert with high stock abundance, although high effort levels are not likely to be supportable if abundance returns to long-term median levels. The GBK stock seems stable, with current abundance and fishing mortality similar to the 20-year average.

The GBK stock encompasses part of Areas 2, 3, and the Outer Cape Management Area. While the assessment noted the female proportion of the GBK stock is increasing slightly, it also cautioned that further increases in effort are not advisable, hence, the need for additional effort reduction and broodstock protection.

NMFS is also aware that recent constraints on participation in several traditional otter trawl fisheries, including the Mid-Atlantic summer flounder, scup, and black sea bass fisheries and the New England multispecies fisheries, and broader use of area closures may result in a shift in non-trap lobster fishing effort to the lobster trap fishery by vessels that have traditionally harvested lobsters by non-trap methods. Further, limited access programs in other lobster management areas have the potential to cause fishermen who do not qualify in that area to shift trap fishing operations to Area 1, the last remaining open access area. An unchecked increase in effort in the lobster trap fishery, as a result of a shift from non-trap to trap gear and/or as a result of an influx of fishing operations from other areas to Area 1, may jeopardize current efforts to achieve the objectives of the ISFMP and rebuild stocks.

For these reasons, NMFS, in consultation with the Commission, is considering proposed rulemaking to address whether and how to limit entry of vessels which have not fished with traps in Area 1 in the past from fishing in Area 1 with traps in the future, or which have not fished with traps in the past from fishing with traps in the future. The proposed rulemaking may include potential eligibility criteria that would prove trap fishing history or trap fishing history in Area 1 prior to the date of this notice. Such proof might include, but is not necessarily limited to documentation of fishing for lobster with traps, documentation of the purchase of lobster trap tags, and/or the election of Area 1 on their Federal

lobster vessel permit. Further, proof may or may not be required for multiple years preceding the date of this notice, for example, proof of Area 1 trap fishing history for the 2008, 2007 and/or 2006 fishing seasons.

Consideration of a control date does not commit the Commission or NMFS to any particular management regime or criteria for entry into the fishery. Fishermen would not be guaranteed future participation in the fishery regardless of their entry date or intensity of participation in the fishery before or after the control date under consideration. NMFS, in consultation with the Commission, may choose to use a different control date, or to give variably weighted consideration to fishermen active in the fishery before and after the control date. NMFS subsequently may choose a different control date or may choose a management regime that does not make use of a control date. Other qualifying criteria, such as, but not limited to, documentation of landings and sales, may be applied for entry. NMFS may also choose to take no further action to control entry or access into the lobster management areas or address the shift in effort from non-trap to trap gear, in which case the control date may be rescinded. Any action will be taken pursuant to the requirements established under the Atlantic Coastal Act. This document, therefore, gives the public notification that interested participants should locate and preserve records that substantiate and verify their participation in the American lobster fishery in Federal waters.

Authority: 16 U.S.C. 1851 note; 16 U.S.C. 5101 *et seq.*

Dated: December 24, 2008.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. E8-31235 Filed 12-31-08; 8:45 am]

BILLING CODE 3510-22-S

Notices

Federal Register

Vol. 74, No. 1

Friday, January 2, 2009

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2008-0121]

Notice of Availability of Evaluations of the Highly Pathogenic Avian Influenza Subtype H5N1 Status of Germany and Poland

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared evaluations of the animal health status of Germany and Poland relative to the H5N1 subtype of highly pathogenic avian influenza (HPAI). The evaluations present our evaluation of the HPAI H5N1 detection, control, and eradication measures in place in Germany and Poland during outbreaks of HPAI in 2006 and 2007, as well as our assessment of the present status of Germany and Poland with respect to HPAI subtype H5N1. We are making these evaluations available to the public for review and comment. If, after the close of the comment period, APHIS can identify no additional risk factors that would indicate that domestic poultry in Germany or Poland continue to be affected with HPAI H5N1, we would conclude that the importation of live birds, poultry carcasses, parts of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from the affected regions of Germany and Poland presents a low risk of introducing HPAI H5N1 into the United States.

DATES: We will consider all comments we receive prior to February 2, 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=2008=0121> 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-2008-0121, 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-2008-0121.

Reading Room: You may read any comments that we receive on the evaluations 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: Mr. Javier Vargas, Animal Scientist, Regionalization Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-0756.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) has the authority to prohibit or restrict the importation into the United States of animals, animal products, and other articles in order to prevent the introduction of diseases and pests into the U.S. livestock and poultry populations.

Highly pathogenic avian influenza (HPAI) is a zoonotic disease of poultry. The H5N1 subtype of HPAI is an extremely infectious and fatal form of the disease. HPAI can strike poultry quickly without any warning signs of infection and, once established, can spread rapidly from flock to flock. HPAI viruses can also be spread by manure, equipment, vehicles, egg flats, crates,

and people whose clothing or shoes have come in contact with the virus. HPAI viruses can remain viable at moderate temperatures for long periods in the environment and can survive indefinitely in frozen material. The H5N1 subtype of HPAI has been of particular concern because it has crossed the species barrier and caused disease in humans.

On April 6, 2006, the German Federal Ministry of Consumer Protection, Food, and Agriculture reported to the World Organization for Animal Health (OIE) an outbreak of HPAI H5N1 in domestic poultry in a turkey flock in the district of Muldenthal in the Federal State of Saxony. This was the only HPAI H5N1 outbreak to occur in domestic poultry in Germany during 2006.

In 2007, Germany reported six outbreaks of HPAI H5N1 in domestic poultry, four in small hobby farms and two outbreaks on large duck farms with 170,000 ducks on each farm. No additional reports of HPAI H5N1 in Germany in either domestic poultry or wild birds were made until October 9, 2008, when a small outbreak occurred in the district of Görlitz in the Federal State of Saxony following the identification of HPAI H5N1 in a wild bird on a nearby lake.

To prevent the introduction of HPAI H5N1 into the United States, APHIS designated Germany's districts of Muldenthal, Torgue-Oschatz, Dobeln, Saalfeld-Rudolstadt, Schwandorf, Neustradt A.D. Aisch, Bamberg, Kitzingen, Erlangen-Hochstadt, Oberhavel, Havelland, Ostprignitz-Ruppin, Potsdam-Mittlemark, Uckermark, Mecklenburg-Strelitz, Prignitz, Jerichower Land, Gorlitz, and Bautzen as regions where HPAI was considered to exist and prohibited the importation of birds, poultry, and poultry products from these regions into the United States.

In a document titled "APHIS' Evaluation of the Status of High Pathogenicity Avian Influenza H5N1 (HPAI H5N1) in Germany" (October 2008), we present the results of our evaluation of the status of HPAI H5N1 in domestic poultry in Germany in light of the actions taken by German authorities since the outbreaks, and document our analysis of the risk associated with allowing the importation of birds, poultry, and poultry products from regions of

Germany into the United States in the aftermath of the outbreaks.

On December 1, 2007, Poland's General Veterinary Inspectorate reported an HPAI H5N1 outbreak in domestic poultry. This first outbreak was detected in broiler turkeys, and between December 1 and December 22, 2007, Poland reported a total of 10 outbreaks to the OIE.

To prevent the introduction of HPAI H5N1 into the United States, APHIS designated Poland's provinces of Warminsko-Mazurskie, Mazowiekie, and Kujawsko-Pomorskie as regions where HPAI was considered to exist, and prohibited the importation of birds, poultry, and poultry products from these provinces into the United States.

In a document titled "APHIS' Evaluation of the Status of High Pathogenicity Avian Influenza H5N1 Virus in Poland" (October 2008), we present the results of our evaluation of the status of HPAI H5N1 in domestic poultry in Poland in light of the actions taken by Polish authorities since the outbreaks, and document our analysis of the risk associated with allowing importation of birds, poultry, and poultry products from Poland into the United States in the aftermath of the outbreaks.

We based our evaluation of Germany's and Poland's HPAI H5N1 status on the following critical factors:

- Each region had been free of outbreaks of the H5N1 subtype in its domestic poultry for at least 3 months as a result of effective control measures taken by a competent veterinary infrastructure;
- HPAI H5N1 was a notifiable disease in each region at the time of the outbreak;
- Each region had an ongoing disease awareness program in place at the time of the outbreak;
- Each region investigated notified or suspected occurrences of the disease;
- Each region had an effective surveillance program in place that supported the detection and investigation of outbreaks;
- Diagnostic and laboratory capabilities within each region were both adequate and effective;
- Each region undertook appropriate eradication and control measures and movement restrictions in response to the outbreaks to prevent further spread of disease; and
- In each region, procedures used for repopulation of affected premises included monitoring to demonstrate that HPAI H5N1 had been eradicated from the premises.

Based on these factors, which are consistent with the OIE's

recommendations for reinstatement for trade with a country that has experienced an HPAI H5N1 outbreak,¹ our evaluations conclude that the German Federal Ministry of Consumer Protection, Food and Agriculture and Poland's General Veterinary Inspectorate were able to effectively control and eradicate HPAI H5N1 in their respective domestic poultry populations and that the German and Polish authorities have adequate control measures in place to rapidly identify, control, and eradicate the disease should it be reintroduced into their respective countries in either wild birds or domestic poultry.

We are making the evaluations available for public comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

If, after the close of the comment period, APHIS can identify no additional risk factors that would indicate that domestic poultry in regions of Germany or Poland continue to be affected with HPAI H5N1, we would conclude that the importation of live birds, poultry carcasses, parts of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions of Germany and Poland presents a low risk of introducing HPAI H5N1 into the United States.

For Germany, we expect we would lift the restrictions we imposed in response to the 2006 and 2007 outbreaks and maintain the restrictions we imposed in response to the October 2008 outbreak until the European Commission lifts the restrictions, at which point we would reevaluate the HPAI H5N1 status of the district of Görlitz in Saxony.

The evaluations may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the evaluations by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the titles of the evaluations when requesting copies.

¹ OIE (2008). Risk Analysis. In, *Terrestrial Animal Health Code*, 17th edition. Paris, World Organization for Animal Health: Chapter 2.2 on Import Risk Analysis; Chapter 10.4 on Avian Influenza. To view the document on the Internet, go to http://www.oie.int/eng/normes/mcode/A_summy.htm?e1d11.

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8-31210 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Solicitation of Input From Stakeholders on the Establishment of the National Institute of Food and Agriculture at the Department of Agriculture

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of public comment period for written stakeholder input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) is requesting written stakeholder input on the establishment of the National Institute of Food and Agriculture (Institute) at the Department of Agriculture (USDA). The establishment of the Institute is mandated in section 251(f) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6971(f)) as added by section 7511(a)(4) of the Food, Conservation, and Energy Act (FCEA) of 2008 (Pub. L. 110-246). All programs and authorities currently delegated to CSREES will transfer to the Institute, no later than October 1, 2009. By this notice, CSREES has been designated to act on behalf of the Secretary of Agriculture (Secretary) in soliciting public comment from interested parties regarding the establishment of the Institute.

DATES: All written comments must be received by Friday, February 6, 2009, to be considered.

ADDRESSES: You may submit comments, identified by CSREES-2008-0004, by any of the following methods:

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

E-mail: Institute@csrees.usda.gov. Include CSREES-2008-0004 in the subject line of the message.

Fax: (202) 720-0289.

Mail: Paper, disk or CD-ROM submissions should be submitted to: Judy Rude; Communications Staff; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Mail Stop 2201; 1400 Independence Avenue, SW.; Washington, DC 20250-2201.

Hand Delivery/Courier: Judy Rude; Communications Staff; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 4236; Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024.

Instructions: All submissions received must include the title "Institute" and CSREES-2008-0004. All comments received will be posted to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Judy Rude, (202) 720-4242 (phone), (202) 690-0289 (fax), or Institute@csrees.usda.gov.

SUPPLEMENTARY INFORMATION:

Additional Comment Procedures

Descriptions of the principles guiding deliberations relative to establishing the Institute are available for review at <http://www.csrees.usda.gov/newsroom/pdfs/Scientists,%20Educators,%20and%20Stakeholders%20Letter.pdf>.

Written comments must be received by close of business, Friday, February 6, 2009, to be considered. All comments, when they become available, may be reviewed on the CSREES Web page for six months.

Background and Purpose

The establishment of the National Institute of Food and Agriculture is mandated in section 251(f) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6971(f)), as added to section 7511(a)(4) of the Food, Conservation, and Energy Act (FCEA) of 2008 (Pub. L. 110-246). The Secretary shall transfer to the Institute, effective not later than October 1, 2009, the authorities (including all budget authorities, available appropriations, and personnel), duties, obligations, and related legal and administrative functions prescribed by law or otherwise granted to the Secretary, the Department, or any other agency or official of the Department under capacity and infrastructure programs; competitive programs; the research, education, economic, cooperative State research programs, cooperative extension and education programs, international programs, and other functions and authorities delegated by the Under Secretary for Research, Education, and Economics (Under Secretary for REE) to the Administrator of CSREES pursuant to section 2.66 of title 7, Code of Federal Regulations (or successor regulations); and any and all other authorities administered by the Administrator of CSREES. The terms "capacity and

infrastructure programs" and "competitive programs" are defined in section 251(f)(1) (7 U.S.C. 6971(f)(1)).

The Institute shall be headed by a Director, who shall be an individual who is a distinguished scientist and appointed by the President. The Secretary has determined that the Director shall report to the Under Secretary for REE, who also holds the title of Chief Scientist of USDA and is responsible for the coordination of research, education, and extension activities of USDA. The Director shall serve for a 6-year term, subject to reappointment for an additional 6-year term; periodically report to the Under Secretary for REE with respect to activities carried out by the Institute; and consult regularly with the Under Secretary for REE to ensure, to the maximum extent practicable, that research of the Institute is relevant to agriculture in the United States and otherwise serves the national interest; and that the research of the Institute supplements and enhances, and does not supplant, research conducted or funded by other Federal agencies. The Director shall exercise all of the authority provided to the Institute by section 251(f) (7 U.S.C. 6971(f)); formulate and administer programs in accordance with policies adopted by the Institute, in coordination with the Under Secretary for REE; establish offices within the Institute; establish procedures for the provision and administration of grants by the Institute; and consult regularly with the National Agricultural Research, Extension, Education, and Economics Advisory Board.

The Director shall organize offices and functions within the Institute to administer fundamental and applied research and extension and education programs. The Director shall ensure the research priorities established by the Under Secretary for REE through the Research, Education and Extension Office are carried out by the offices and functions of the Institute, where applicable. Per 7 U.S.C. 6971(e)(1), the Under Secretary for REE is required to organize within the Office of the Under Secretary for REE six Divisions, to be known collectively as the 'Research, Education, and Extension Office', which shall coordinate the research programs and activities of the Department.

The Director shall determine an appropriate balance between fundamental and applied research programs and functions to ensure future research needs are met and designate staff, as appropriate, to assist in carrying out this function. The Director shall promote the use and growth of grants

awarded through a competitive process and designate staff, as appropriate, to assist in carrying out this function. Finally, the Director shall ensure that the offices and functions established within the Institute are effectively coordinated for maximum efficiency.

Implementation Plans

CSREES plans to consider stakeholder input received from written comments in developing a proposed organization for approval by USDA and with an implementation date of not later than October 1, 2009.

Done at Washington, DC, this 29th day of December, 2008.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. E8-31258 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-22-P

DEPARTMENT OF AGRICULTURE

Forest Service

Bend/Ft. Rock Ranger District; Deschutes National Forest; Oregon; Kapka Butte Sno-Park Construction

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The USDA, Forest Service, will prepare an Environmental Impact Statement (EIS) on a proposed action to construct a sno-park, designate motorized and non-motorized over-snow trails to link the parking facility to existing snowmobile and nordic trail systems, and designate new over-snow dog-friendly snowshoe and skier trails to enhance recreational opportunities from the new facility. The proposed sno-park would be located on National Forest lands between Kapka Butte and the junction of Forest Road 46 (Cascade Lakes Highway) and Forest Road 45 (Sunriver cutoff). The proposed sno-park area is located about 30 miles west of Bend, Oregon; it is located in Section 35, Township 18S, Range 9E. The alternatives will include the proposed action, no action, and additional alternatives that respond to issues generated through the scoping process. The agency will give notice of the full environmental analysis and decision making process so interested and affected people may participate and contribute to the final decision.

DATES: Comments concerning the scope of the analysis must be received by 30 days following the date that this notice appears in the **Federal Register**.

ADDRESSES: Send written comments to Shane Jeffries, District Ranger, Bend/Ft. Rock Ranger District, 1230 NE 3rd St., Suite A-262, Bend, OR 97701.

FOR FURTHER INFORMATION CONTACT:

Marv Lang, Project Leader, Bend/Ft. Rock Ranger District, 1230 NE 3rd St., Suite A-262, Bend, Oregon 97701, phone (541) 383-4793. E-mail melang@fs.fed.us.

Responsible Official. The responsible official will be Shane Jeffries, District Ranger, Bend-Fort Rock Ranger District, 1230 NE Third St., Ste. A-262, Bend, OR 97701.

SUPPLEMENTARY INFORMATION:

Purpose and Need. The Deschutes National Forest sees a need to provide high elevation parking that will enhance a variety of winter recreation opportunities near Mt. Bachelor. On most weekend and holiday periods during the wintertime near Mt. Bachelor, it is not unusual to see parking lots full of vehicles, causing over-flow parking in inappropriate locations such as chain-up areas. This has been a progressive condition since the mid-1990s and has reached a point where it has become a public safety concern. More winter uses, such as snowshoeing, backcountry skiing and skijoring, have become more popular in recent years. These newer uses on top of the already high use that the area near Mt. Bachelor receives have created the congestion that occurs at all of the sno-parks. A result of the crowded conditions is inappropriate parking along the Cascade Lake Highway during weekends and holidays, causing traffic problems for the traveling public, emergency vehicles, and snow plowing equipment. This persistent condition demonstrates a need for additional safe parking facilities that provide access to over snow trail systems during more marginal snow conditions than the lower elevation sno-parks currently provide. It's also important that this occurs in a location where regular snowplowing can also be accomplished in an economically feasible manner.

Proposed Action. The Forest Service is proposing to build a new sno-park near Kapka Butte to provide more high elevation parking for winter recreationists along an established snowplowing route. The proposed facility would provide for a mix of vehicle parking, including vehicles towing trailers and some slots designed for smaller vehicles. The proposed parking facility would include approximately 70 slots for trailers, and 40 slots for non-trailer vehicles. Trail links to existing snowmobile and nordic trails would also be provided as well as

new proposed trails for nordic skiing, snowshoeing and skiing with dogs.

Comment. Public comments about this proposal are requested in order to assist in identifying issues, determine how to best manage the resources, and to focus the analysis. Comments received to this notice, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR parts 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

A draft EIS will be filed with the Environmental Protection Agency (EPA) and available for public review by Spring 2009. The EPA will publish a Notice of Availability (NOA) of the draft EIS in the **Federal Register**. The final EIS is scheduled to be available Autumn 2009.

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**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of a draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions [*Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978)]. Also, environmental objections that could be raised at the draft EIS stage but that are not raised until after completion of the final EIS may be waived or dismissed by the courts [*City of Angoon v. 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 them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft EIS of the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

In the final EIS, the Forest Service is required to respond to substantive comments received during the comment period for the draft EIS. The Forest Service is the lead agency and the responsible official is the Bend-Fort Rock District Ranger, Deschutes National Forest. The responsible official will decide where, and whether or not to construct the sno-park and associated trails. The responsible official will also decide how to mitigate impacts of these actions and will determine when and how monitoring of effects will take place.

The Kapka Butte Sno-park Project decision and the reasons for the decision will be documented in the Record of Decision. That decision will be subject to Forest Service Appeal Regulations (35 CFR Part 215).

Sean A. Ferrell,

Assistant District Ranger.

[FR Doc. E8-31118 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 0612242720-81597

RIN 0648-ZB55

Availability of Grant Funds for Fiscal Year 2009

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: NOAA publishes this notice to supplement the agency's solicitation

for applications published on July 11, 2008 in an action entitled "Omnibus Notice Announcing the Availability of Grant Funds for Fiscal Year 2009". This notice announces 13 additional programs that are soliciting applications for FY 2009 funding.

DATES: Proposals must be received by the date and time indicated under each program listing in the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: Proposals must be submitted to the addresses listed in the **SUPPLEMENTARY INFORMATION** section of this notice for each program. The **Federal Register** and Federal Funding Opportunity (FFO) notices may be found on the Grants.gov Web site. The URL for Grants.gov is <http://www.grants.gov>.

FOR FURTHER INFORMATION CONTACT: Please contact the person listed within this notice as the information contact under each program.

SUPPLEMENTARY INFORMATION: Applicants must comply with all requirements contained in the Federal Funding Opportunity announcement for each of the programs listed in this omnibus notice. These Federal Funding Opportunities are available at <http://www.grants.gov>. The list of entries below describes the basic information and requirements for competitive grant/cooperative agreement programs offered by NOAA. These programs are open to any applicant who meets the eligibility criteria provided in each entry. To be considered for an award in a competitive grant/cooperative agreement program, an eligible applicant must submit a complete and responsive application to the appropriate program office. An award is made upon conclusion of the evaluation and selection process for the respective program.

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3. FY09 Hawaii Seafood Program
4. New Bedford Harbor Restoration Projects (IV)
5. Pacific Coastal Salmon Recovery Fund
6. Proactive Species Conservation Program

National Ocean Service (NOS)

1. Coastal and Estuarine Land Conservation Program—FY 2010 Competition
2. Coral Reef NGO Partnership
3. FY09 Bay Watershed Education and Training Program, Adult and Community Watershed Education in the

Monterey Bay

National Weather Service (NWS)

1. Hydrologic Research
2. Remote Community Alert Systems Program 2009

Office of the Under Secretary (USEC)

1. Dr. Nancy Foster Scholarship Program
2. Environmental Literacy Grants: Science On a Sphere Network Capacity Building

IV. NOAA Project Competitions Listed by NOAA Mission Goals

1. Protect, Restore and Manage the Use of Coastal and Ocean Resources Through Ecosystem-Based Management

Coastal areas are among the most developed in the Nation. More than half the population lives on less than one-fifth of the land in the contiguous United States. Furthermore, employment in near shore areas is growing three times faster than population. Coastal and marine waters support over 28 million jobs and provide a tourism destination for nearly 90 million Americans a year. The value of the ocean economy to the United States is over \$115 billion. The value added annually to the national economy by the commercial and recreational fishing industry alone is over \$48 billion. U.S. aquaculture sales total almost \$1 billion annually. With its Exclusive Economic Zone of 3.4 million square miles, the United States manages the largest marine territory of any nation in the world. Funded proposals should help achieve the following outcomes:

1. Healthy and productive coastal and marine ecosystems that benefit society.
2. A well-informed public that acts as a steward of coastal and marine ecosystems.

Program Names

1. Dr. Nancy Foster Scholarship Program.
2. Coral Reef NGO Partnership.
3. Proactive Species Conservation Program.
4. FY09 Hawaii Seafood Program.
5. FY09 Bay Watershed Education and Training Program, Adult and Community Watershed Education in the Monterey Bay.
6. 2010 Herring Research Set-Aside (RSA).
7. 2010 Mid-Atlantic Research Set-Aside (RSA).
8. Coastal and Estuarine Land Conservation Program—FY 2010 Competition.
9. Pacific Coastal Salmon Recovery Fund.
10. New Bedford Harbor Restoration Projects (IV).

2. Understand Climate Variability and Change To Enhance Society's Ability To Plan and Respond

Climate shapes the environment, natural resources, economies, and social systems that people depend upon worldwide. While humanity has learned to contend with some aspects of climate's natural variability, major climatic events, combined with the stresses of population growth, economic growth, public health concerns, and land-use practices, can impose serious consequences on society. The 1997–98 El Niño, for example, had a \$25 billion impact on the U.S. economy—property losses were \$2.6 billion and crop losses approached \$2 billion. Long-term drought leads to increased and competing demands for fresh water with related effects on terrestrial and marine ecosystems, agricultural productivity, and even the spread of infectious diseases. Decisions about mitigating climate change also can alter economic and social structures on a global scale. We can deliver reliable climate information in useful ways to help minimize risks and maximize opportunities for decisions in agriculture, public policy, natural resources, water and energy use, and public health. We continue to move toward developing a seamless suite of weather and climate products. The Climate Goal addresses predictions on time scales of up to decades or longer.

Funded proposals should help achieve the following outcomes:

1. A predictive understanding of the global climate system on time scales of weeks to decades with quantified uncertainties sufficient or making informed and reasoned decisions.

2. Climate-sensitive sectors and the climate-literate public effectively incorporating NOAA's climate products into their plans and decisions.

Program Names

1. Coral Reef NGO Partnership.
2. Proactive Species Conservation Program.
3. Hydrologic Research.

3. Serve Society's Needs for Weather and Water Information

Floods, droughts, hurricanes, tornadoes, tsunamis, wildfires, and other severe weather events cause \$11 billion in damages each year in the United States. Weather is directly linked to public health and safety, and nearly one-third of the U.S. economy (about \$3 trillion) is sensitive to weather and climate. With so much at stake, NOAA's role in understanding, observing, forecasting, and warning of

environmental events is expanding. With our partners, we seek to provide decision makers with key observations, analyses, predictions, and warnings for a range of weather and water conditions, including those related to water supply, air quality, space weather, and wildfires. Businesses, governments, and nongovernmental organizations are getting more sophisticated about how to use this weather and water information to improve operational efficiencies, to manage environmental resources, and to create a better quality of life. On average, hurricanes, tornadoes, tsunamis, and other severe weather events cause \$11 billion in damages per year. Weather, including space weather, is directly linked to public safety and about one-third of the U.S. economy (about \$3 trillion) is weather sensitive. With so much at stake, NOAA's role in observing, forecasting, and warning of environmental events is expanding, while economic sectors and its public are becoming increasingly sophisticated at using NOAA's weather, air quality, and water information to improve their operational efficiencies and their management of environmental resources, and quality of life.

Funded proposals should help achieve the following outcomes:

1. Reduced loss of life, injury, and damage to the economy.
2. Better, quicker, and more valuable weather and water information to support improved decisions.
3. Increased customer satisfaction with weather and water information and services.

Program Names

1. Remote Community Alert Systems Program 2009.
2. Hydrologic Research.

4. Provide Critical Support for NOAA's Mission

Strong, effective, and efficient support activities are necessary for us to achieve our Mission Goals. Our facilities, ships, aircraft, environmental satellites, data processing systems, computing and communication systems, and our approach to management provide the foundation of support for all of our programs. This critical foundation must adapt to evolving mission needs and, therefore, is an integral part of our strategic planning. It also must support U.S. homeland security by maintaining continuity of operations and by providing NOAA services, such as civil alert relays through NOAA Weather Radio and air dispersion forecasts, in response to national emergencies. NOAA ships, aircraft, and environmental satellites are the

backbone of the global Earth observing system and provide many critical mission support services. To keep this capability strong and current with our Mission Goals, we will ensure that NOAA has adequate access to safe and efficient ships and aircraft through the use of both NOAA platforms and those of other agency, academic, and commercial partners. We will work with academia and partners in the public and private sectors to ensure that future satellite systems are designed, developed, and operated with the latest technology. Leadership development and program support are essential for achieving our Mission Goals. We must also commit to organizational excellence through management and leadership across a "corporate" NOAA. We must continue our commitment to valuing NOAA's diverse workforce, including effective workforce planning strategies designed to attract, retain and develop competencies at all levels of our workforce. Through the use of business process re-engineering, we will strive for state-of-the-art, value-added financial and administrative processes. NOAA will ensure state-of-the-art and secure information technology and systems. By developing long-range, comprehensive facility planning processes, NOAA will be able to ensure right-sized, cost-effective, and safe facilities.

Funded proposals should help achieve the following outcomes:

1. A dynamic workforce with competencies that support NOAA's mission today and in the future.

Program Names

1. Environmental Literacy Grants: Science on a Sphere Network Capacity Building.
5. *Support the Nation's Commerce With Information for Safe, Efficient, and Environmentally Sound Transportation*

Safe and efficient transportation systems are crucial to the U.S. economy. The U.S. marine transportation system ships over 95 percent of the tonnage and more than 20 percent by value of foreign trade through U.S. ports, including 48 percent of the oil needed to meet America's energy demands. At least \$4 billion is lost annually due to economic inefficiencies resulting from weather related air-traffic delays. Improved surface weather forecasts and specific user warnings would reduce the 7,000 weather related fatalities and 800,000 injuries that occur annually from crashes on roads and highways. The injuries, loss of life, and property damage from weather-related crashes cost an average of \$42 billion annually.

We provide information, services, and products for transportation safety and for increased commerce on roads, rails, and waterways. We will improve the accuracy of our information for marine, aviation, and surface weather forecasts, the availability of accurate and advanced electronic navigational charts, and the delivery of real-time oceanographic information. We seek to provide consistent, accurate, and timely positioning information that is critical for air, sea, and surface transportation. We will respond to hazardous material spills and provide search and rescue routinely to save lives and money and to protect the coastal environment. We will work with port and coastal communities and with Federal and state partners to ensure that port operations and development proceed efficiently and in an environmentally sound manner. We will work with the Federal Aviation Administration and the private sector to reduce the negative impacts of weather on aviation without compromising safety. Because of increased interest by the public and private sectors, we also will expand weather information for marine and surface transportation to enhance safety and efficiency.

Funded proposals should help achieve the following outcomes:

1. Safe, secure, efficient, and seamless movement of goods and people in the U.S. transportation system.
2. Environmentally sound development and use of the U.S. transportation system.

Program Names

1. No programs are currently soliciting proposals for this mission goal.

I. Background

Each of the following grant opportunities provide: a description of the program, funding availability, statutory authority, catalog of federal domestic assistance (CFDA) number, application deadline, address for submitting proposals, information contacts, eligibility requirements, cost sharing requirements, and intergovernmental review under Executive Order 12372.

II. Electronic Access

The full funding announcement for each program is available via the Grants.gov Web site at: <http://www.grants.gov>. Electronic applications for the NOAA Programs listed in this announcement may be accessed, downloaded, and submitted to that Web site. The due dates and times for paper and electronic submissions are

identical. NOAA strongly recommends that you do not wait until the application deadline to begin the application process through Grants.gov. Your application must be received and validated by Grants.gov no later than the due date and time.

Please Note: Validation or rejection of your application by Grants.gov may take up to 2 business days after your submission. Please consider the Grants.gov validation/rejection process in developing your application submission time line.

Grants.gov

Getting started with Grants.gov is easy. Users should note that there are two key features on the Web site: Find Grant Opportunities and Apply for Grants. The site is designed to support these two features and your use of them.

While you can begin searching for grant opportunities immediately, it is recommended that you complete the steps to Get Started (below) ahead of time. This will help ensure you are ready to go when you find an opportunity for which you would like to apply.

Applications From Individuals

In order for you to apply as an individual the announcement must specify that the program is open to individuals and it must be published on the Grants.gov Web site. Individuals must register with the Credential Provider (see Step 3 below) and with Grants.gov (see Step 4 below). Individuals do not need a DUNS number to register (see Step 4 below) and submit their applications. The system will generate a default value in that field.

Grants.gov Application Submission and Receipt Procedures

This section provides the application submission and receipt instructions for NOAA program applications. Please read the following instructions carefully and completely.

1. *Electronic Delivery.* NOAA is participating in the Grants.gov Initiative that provides the Grant Community a single site to find and apply for grant funding opportunities. NOAA encourages applicants to submit their applications electronically through: http://www.grants.gov/applicants/apply_for_grants.jsp.

2. *The following describes what to expect when applying on line using Grants.gov/Apply:*

a. *Instructions.* On the site, you will find step-by-step instructions which enable you to apply for NOAA funds. The Grants.gov/Apply feature includes a

simple, unified application process that makes it possible for applicants to apply for grants online. There are six "Get Started" steps to complete at Grants.gov. The information applicants need to understand and execute the steps can be found at: http://www.grants.gov/applicants/get_registered.jsp.

Applicants should read the Get Started steps carefully. The site also contains registration checklists to help you walk through the process. NOAA recommends that you download the checklists and prepare the information requested before beginning the registration process. Reviewing and assembling required information before beginning the registration process will make the process fast and smooth and save time.

b. *DUNS Requirement.* All applicants applying for funding, including renewal funding, must have a Dun and Bradstreet Universal Data Numbering System (DUNS) number. The DUNS number must be included in the data entry field labeled "Organizational Duns" on the form SF-424. Instructions for obtaining a DUNS number can be found at the following Web site: http://www.grants.gov/applicants/get_registered.jsp.

c. *Central Contractor Registry and Credential Provider Registration.* In addition to having a DUNS number, applicants applying electronically through Grants.gov must register with the Federal Central Contractor Registry and with a Credential Provider. The <http://www.grants.gov> Web site at http://www.grants.gov/applicants/get_registered.jsp provides step-by-step instructions for registering in the Central Contractor Registry and for registering with a credential provider. All applicants filing electronically must register with the Central Contractor Registry and receive credentials from the Grants.gov credential provider in order to apply on line. Failure to register with the Central Contractor Registry and credential provider will result in your application being rejected by the Grants.gov portal.

The registration process is a separate process from submitting an application. Applicants are, therefore, encouraged to register early. The registration process can take approximately two weeks to be completed. Therefore, registration should be done in sufficient time to ensure it does not impact your ability to meet required submission deadlines. You will be able to submit your application online anytime after you receive your e-authentication credentials.

d. *Electronic Signature.* Applications submitted through Grants.gov constitute

submission as electronically signed applications. The registration and e-authentication process establishes the Authorized Organization Representative (AOR). When you submit the application through Grants.gov, the name of your authorized organization representative on file will be inserted into the signature line of the application. Applicants must register the individual who is able to make legally binding commitments for the applicant organization as the Authorized Organization Representative.

3. *Instructions on how to submit an electronic application to NOAA via Grants.gov/Apply:*

Grants.gov has a full set of instructions on how to apply for funds on its Web site at: http://www.grants.gov/applicants/apply_for_grants.jsp. The following provides simple guidance on what you will find on the Grants.gov/Apply site. Applicants are encouraged to read through the page entitled, "Complete Application Package" before getting started. Grants.gov allows applicants to download the application package, instructions and forms that are incorporated in the instructions, and work off line. In addition to forms that are part of the application instructions, there will be a series of electronic forms that are provided utilizing an Adobe Reader.

Note for the Adobe Reader: Grants.gov is only compatible with versions 8.1.1 and above. Please do not use lower versions of the Adobe Reader.

Mandatory Fields on Adobe Reader Forms

In the Adobe forms you will note fields that appear with a yellow background and red outline color. These fields are mandatory and must be completed to successfully submit your application. The Adobe forms are designed to fill in common required fields such as the applicant name and address, DUNS number, etc., on all Adobe electronic forms. To trigger this feature, an applicant must complete the SF-424 information first. Once it is completed the information will transfer to the other forms.

Customer Support

The Grants.gov Web site provides customer support via (800) 518-4726 (this is a toll-free number) or through e-mail at support@grants.gov. The Contact Center is open from 7 a.m. to 9 p.m. Eastern time, Monday through Friday, except federal holidays, to address Grants.gov technology issues. For

technical assistance to program related questions, contact the number listed in the Program Section of the program you are applying for.

4. Timely Receipt Requirements and Proof of Timely Submission

a. **Electronic Submission.** All applications must be received by http://www.grants.gov/applicants/apply_for_grants.jsp by the Time on the due date established for each program. Proof of timely submission is automatically recorded by Grants.gov. An electronic time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant will receive an acknowledgement of receipt and a tracking number from Grants.gov with the successful transmission of their application. Applicants should print this receipt and save it, along with facsimile receipts for information provided by facsimile, as proof of timely submission. When NOAA successfully retrieves the application from Grants.gov, Grants.gov will provide an electronic acknowledgment of receipt to the e-mail address of the AOR. Proof of Timely submission shall be the date and time that Grants.gov receives your application. Applications received by Grants.gov, after the established due date for the program will be considered late and will not be considered for funding by NOAA.

Please Note: Validation or rejection of your application by Grants.gov may take up to 2 business days after your submission. Please consider the Grants.gov validation/rejection process in developing your application submission time line.

NOAA suggests that applicants submit their applications during the operating hours of Grants.gov, so that if there are questions concerning transmission, operators will be available to walk you through the process. Submitting your application during the Contact Center hours will also ensure that you have sufficient time for the application to complete its transmission prior to the application deadline. Applicants using dial-up connections should be aware that transmission may take some time before Grants.gov receives it. Grants.gov will provide either an error or a successfully received transmission message. The Grants.gov program office reports that some applicants abort the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application. Uploading and transmitting many files, particularly electronic forms with

associated XML schemas, will take some time to be processed.

Evaluation Criteria and Selection Procedures

NOAA has standardized the evaluation and selection process for its competitive assistance programs. There are two separate sets of evaluation criteria and selection procedures (see below), one for project proposals, and the other for fellowship, scholarship, and internship programs.

Project Proposals

Review and Selection Process: Some project proposals may include a pre-application process that provides for feedback to applicants that responded to a call for letters of intent or pre-proposals; however, not all programs will include this pre-application. If a program has a pre-application process, it will be described in the Summary Description section of the announcement and the deadline will be specified in the Application Deadline section.

Upon receipt of a full application by NOAA, an initial administrative review will be conducted to determine compliance with requirements and completeness of the application. A merit review will also be conducted to produce a rank order of the proposals. The NOAA Program Officer may review the ranking of the proposals and make recommendations to the Selecting Official based on the administrative and/or merit review(s) and selection factors listed below. The Selecting Official selects proposals after considering the administrative and/or merit review(s) and recommendations of the Program Officer. In making the final selections, the Selecting Official will award in rank order unless the proposal is justified to be selected out of rank order based upon one or more of the selection factors below. The Program Officer and/or Selecting Official may negotiate the funding level of the proposal. The Selecting Official makes final award recommendations to the Grants Officer authorized to obligate the funds.

Evaluation Criteria

Each reviewer (each announcement will specify the number and type of reviewers) will individually evaluate and rank proposals using the following evaluation criteria:

1. **Importance and/or relevance and applicability of a proposed project to the program goals:** This ascertains whether there is intrinsic value in the proposed work and/or relevance to

NOAA, Federal (other than NOAA), regional, state, or local activities.

2. **Technical/scientific merit:** This assesses whether the approach is technically sound and/or innovative, if the methods are appropriate, and whether there are clear project goals and objectives.

3. **Overall qualifications of applicants:** This ascertains whether the applicant possesses the necessary education, experience, training, facilities, and administrative resources to accomplish the project.

4. **Project costs:** The project's budget is evaluated to determine if it is realistic and commensurate with the project needs and timeframe.

5. **Outreach and education:** NOAA assesses whether this project provides a focused and effective education and outreach strategy regarding its mission to protect the Nation's natural resources.

Selection Factors

The merit review ratings will be used to provide a rank order to the Selecting Official for final funding recommendations. A Program Officer may first make recommendations to the Selecting Official applying the selection factors listed below. The Selecting Official shall award in the rank order unless the proposal is justified to be selected out of rank order based upon one or more of the following factors:

1. Availability of funding.
2. Balance/distribution of funds:
 - a. Geographically,
 - b. By type of institutions,
 - c. By type of partners,
 - d. By research areas, and
 - e. By project types.
3. Whether the project duplicates other projects funded or considered for funding by NOAA or other federal agencies.
4. Program priorities and policy factors.
5. Applicant's prior award performance.
6. Partnerships and/or participation of targeted groups.
7. Adequacy of information necessary for NOAA to make a National Environmental Policy Act determination and draft necessary documentation before funding recommendations are made to the Grants Officer.

Fellowship, Scholarship and Internship Programs Review and Selection Process

Some fellowship, scholarship and internship programs may include a pre-application process that provides for feedback to the applicants that have responded to a call for letters of intent or pre-proposals; however, not all programs will include this pre-

application. If a program has a pre-application process, the process will be described in the Summary Description section of the announcement and the deadline will be specified in the Application Deadline section. Upon receipt of a full application by NOAA, an initial administrative review will be conducted to determine compliance with requirements and completeness of the application.

A merit review will also be conducted to produce a rank order of the proposals. The NOAA Program Officer may review the ranking of the proposals and make recommendations to the Selecting Official based on the administrative and/or merit review(s) and selection factors listed below. The Selecting Official selects proposals after considering the administrative and/or merit review(s) and recommendations of the Program Officer. In making the final selections, the Selecting Official will award in rank order unless the proposal is justified to be selected out of rank order based upon one or more of the selection factors below. The Program Officer and/or Selecting Official may negotiate the funding level of the proposal. The Selecting Official makes final award recommendations to the Grants Officer authorized to obligate the funds.

Evaluation Criteria

Each reviewer (each announcement will specify the number and type of reviewers) will individually evaluate and rank proposals using the following evaluation criteria.

1. Academic record and statement of career goals and objectives of the student.
2. Quality of project and applicability to program priorities.
3. Recommendations and/or endorsements of the student.
4. Additional relevant experience related to diversity of education; extra-curricular activities; honors and awards; and interpersonal, written, and oral communications skills.
5. Financial need of the student.

Selection Factors

The merit review ratings will be used to provide a rank order by the Selecting Official for final funding recommendations. A Program Officer may first make recommendations to the Selecting Official by applying the selection factors listed below. The Selecting Official shall award in the rank order unless the proposal is justified to be selected out of rank order based upon one or more of the following factors:

1. Availability of funds.

2. Balance/distribution of funds:
 - a. Across academic disciplines,
 - b. By types of institutions, and
 - c. Geographically.
3. Program-specific objectives.
4. Degree in scientific area and type of degree sought.

III. NOAA Project Competitions

National Marine Fisheries Service (NMFS)

1. 2010 Herring Research Set-Aside (RSA)

Summary Description: NMFS, in cooperation with the New England Fishery Management Council (Council), is soliciting 2010 Atlantic Herring (herring) Research Set-Aside (RSA) proposals that address research priorities concerning the herring fishery. The Herring RSA Program was created by the Council as a vehicle to fund research projects through the sale of research quota. Under this program, the Council may set aside up to 3 percent of the total allowable landings (TAL) to fund selected projects. Proceeds from the sale of research quota are used to pay for research costs and to compensate fishing vessels that harvest research quota. Participating vessels may be authorized to harvest and land fish in excess of Federal possession limits and/or during fishery closures. No Federal funds are provided for research under this notification. NMFS and the Council will give priority to funding proposals addressing the research needs identified in Section I-B of this document.

Funding Availability: No Federal funds are provided for research under this notification, but rather the opportunity to fish with the catch sold to generate income. Individual research projects may apply for the use of more than one herring research set-aside allocation from the 2010 fishing year. The research compensation trips must be conducted in the management area from which the set-aside was derived. In addition, research quota must be harvested in the same fishing year from which it was distributed. No more than 50 percent of an allocated set-aside should be taken before the research begins. Research quota does not need to be harvested during research activities. To establish an approximate value on research quota, the value of herring when it is harvested in 2010 must be estimated. This Federal Funding Opportunity (FFO) uses an estimated price based on the average 2008 price of \$248 per metric ton (mt), or \$0.11 per lb, as established through herring dealer reports. By requiring researchers to use this price in requesting RSA quota, all

proposals will relate herring catch to research costs similarly. The Federal Government may issue an Exempted Fishing Permit (EFP), which may provide special fishing privileges in response to research proposals selected under this program. Funds generated from RSA landings shall be used to cover the cost of the research activities, including vessel costs, and to compensate vessels for expenses incurred during the harvest of research quota. For example, the funds may be used to pay for gear modifications, monitoring equipment, additional provisions (e.g., fuel, ice, food for scientists), or the salaries of research personnel.

The Federal Government is not liable for any costs incurred by the researcher or vessel owner should the sale of research quota not fully reimburse the researcher or vessel owner for their expenses. Any additional funds generated through the sale of fish harvested under the research quota above the cost of research activities shall be retained by the vessel owner as compensation for the use of his/her vessel. If a research project is terminated for any reason prior to completion, any funds collected from the catch sold to pay for research expenses must be turned over to the U.S. Treasury. RSA quota available to applicants under the 2010 Herring RSA Program will be established through the 2010 quota specification rulemaking process. The Council is scheduled to establish the 2010 herring quota, including the RSA quota, in 2009. Based on Council recommendations, NMFS may choose to adopt less than 3 percent of TAL as a set-aside, or decide not to adopt any set-aside for a given fishery. The value of RSA quota will be dictated by market conditions prevailing at the time the compensation fishing trips are conducted. To help researchers develop proposals and proposal budgets for the 2010 Herring RSA Program, recent quota amount and quota value information is listed below as an example. This information is for guidance purposes only; it does not reflect actual RSA quota amounts or quota values that will be in effect for the 2010 fishing year. RSA quota amounts are based on 2008/2009 FMP specifications. RSA quota values are based on NMFS dealer database landings information. This information is listed below in the following format: Management Area/ RSA quota amount (mt/lbs)/RSA quota total value. Management Area 1A/1350 mt/2,976,240 lbs/\$334,800, Management Area 1B/300 mt/661,386 lbs/\$74,400, Management Area 2/900 mt/1,984,160

lbs/\$223,200, Management Area 3/1800 mt/3,968,320 lbs/\$446,400.

Statutory Authority: Statutory authority for this program is provided under 303(b)(11), 402(e), and 404(c) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1853(b)(11), 16 U.S.C. 1881a(e), and 16 U.S.C. 1881(c), respectively. Statutory authority for entering into cooperative agreements and other financial agreements with non-profit organizations is found at 15 U.S.C. 1540. Amendment 1 of the Herring FMP established the Herring RSA Program (72 FR 11251; March 12, 2007), codified at 50 CFR 648.207.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.454, Unallied Management Projects.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. EST on February 17, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: To apply for this NOAA Federal funding opportunity, please submit applications to <http://www.grants.gov> and use the following funding opportunity number NMFS-NEFSC-2010-2001653.

Applicants who do not have Internet access may submit their application to Cheryl A. Corbett, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543.

Information Contacts: Information may be obtained from Paul Howard, Executive Director, New England Fishery Management Council, by phone at 978-465-0492, or fax at 978-465-3116; or Cheryl A. Corbett, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543, or by phone at 508-495-2070, or fax at 508-495-2004, or via e-mail at cheryl.corbett@noaa.gov, or Ryan Silva, Cooperative Research Liaison, NMFS, Northeast Regional Office by phone at 978-281-9326, or via e-mail at ryan.silva@noaa.gov.

Eligibility: 1. Eligible applicants include institutions of higher education, hospitals, other nonprofits, commercial organizations, individuals, and state, local, and Native American tribal governments. Federal agencies and institutions are not eligible to receive Federal assistance under this notice. Additionally, employees of any Federal agency or Regional Fishery Management

Council are ineligible to submit an application under this program. However, Council members who are not Federal employees may submit an application. 2. DOC/NOAA supports cultural and gender diversity and encourages women and minority individuals and groups to submit applications to the RSA program. In addition, DOC/NOAA is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. DOC/NOAA encourages proposals involving any of the above institutions. 3. DOC/NOAA encourages applications from members of the fishing community and applications that involve fishing community cooperation and participation.

Cost Sharing Requirements: None required.

Intergovernmental Review: Applicants will need to determine if their state participates in the intergovernmental review process. This information can be found at the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>. This information will assist applicants in providing either a Yes or No response to Item 16 of the Application Form, SF-424, entitled "Application for Federal Assistance."

2. 2010 Mid-Atlantic Research Set-Aside (RSA)

Summary Description: NMFS, in cooperation with the Mid-Atlantic Fishery Management Council (Council), is soliciting proposals under the 2010 Mid-Atlantic Research Set-Aside (RSA) Program that address research priorities concerning the summer flounder, scup, black sea bass, Loligo squid, Illex squid, Atlantic mackerel, butterfish, bluefish, and tilefish fisheries. The Mid-Atlantic RSA Program was created by the Council as a vehicle to fund research projects through the sale of research quota. Under this program, the Council may set aside up to 3 percent of the total allowable landings (TAL) from the above listed species to fund selected projects. Proceeds from the sale of research quota are used to pay for research costs and to compensate fishing vessels that harvest research quota.

Participating vessels may be authorized to harvest and land fish in excess of Federal possession limits and/or during fishery closures. No Federal funds are provided for research under this notification. NMFS and the Council will give priority to funding proposals

addressing the research needs identified in Section I-B of this document.

Funding Availability: No Federal funds are provided for research under this notification, but rather the opportunity to fish with the catch sold to generate research funds and to provide compensation for harvesting of RSA quota. The Federal Government may issue an exempted fishing permit (EFP) to selected projects, which may provide special fishing privileges, such as exemption from possession limits and fishery closures. Funds generated from RSA landings shall be used to cover the cost of the research activities, including vessel costs, and to compensate boats for expenses incurred during the collection of the set-aside species. For example, the funds may be used to pay for gear modifications, monitoring equipment, additional provisions (e.g., fuel, ice, food for scientists), or the salaries of research personnel. The Federal Government is not liable for any costs incurred by the researcher or vessel owner should the sale of RSA quota not fully reimburse the researcher or vessel owner for his/her expenses. Any additional funds generated through the sale of fish harvested under the research quota above the cost of the research activities shall be retained by the vessel owner as compensation for the use of his/her vessel. If a research project is terminated for any reason prior to completion, any funds collected from the catch sold to pay for research expenses must be turned over to the U.S. Treasury. The Council, in consultation with the Commission, will incorporate RSA quotas for each of the set-aside species for the 2010 fishing year into the Council's annual quota specification recommendations. NMFS will consider the recommended level of RSA as part of the associated rulemaking process. RSA quota available to applicants under the 2010 Mid-Atlantic RSA Program will be established through the 2010 quota specification rulemaking process. The Council is scheduled to establish quotas, including RSA quotas, by the end of 2009. Based on Council recommendations, NMFS may choose to adopt less than 3 percent of TAL as a set-aside, or decide not to adopt any set-aside for a given fishery.

The value of RSA quota will be dictated by market conditions prevailing at the time the compensation fishing trips are conducted. To help researchers develop proposals and proposal budgets for the 2010 Mid-Atlantic RSA Program, recent quota amount and quota value information is listed below. This information is for guidance purposes only; it does not reflect actual RSA

quota amounts or quota values that will be in effect for fishing year 2010. RSA quota amounts are based on 2009 FMP specifications proposed by the Council. RSA quota values are based on landings data taken from Fisheries of the United States, 2007. This information is listed below in the following format: Species/RSA quota amount (lb)/RSA quota total value/RSA value per pound. Summer flounder/553,500 lb/\$1,311,795/\$2.37 lb, Scup/220,200 lb/\$195,978/\$0.89 lb, Black sea bass/69,000 lb/\$195,270/\$2.83 lb, Loligo squid/1,124,356 lb/\$966,946/\$0.86 lb, Bluefish/743,965 lb/\$260,388/\$0.35 lb, Butterfish/33,069 lb/\$15,542/\$0.47 lb, Illex squid/1,587,328 lb/\$301,592/\$0.19 lb (no Illex squid was requested), Atlantic mackerel/7,645,948 lb/\$917,514/\$0.12 (no Atlantic mackerel was requested), Tilefish/0 lb/\$0/\$0 lb.

Statutory Authority: Statutory authority for this program is provided under sections 303(b)(11), 402(e), and 404(c) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1853(b)(11), 16 U.S.C. 1881a(e), and 16 U.S.C. 1881(c), respectively. Statutory authority for entering into cooperative agreements and other financial agreements with non-profit organizations is found at 15 U.S.C. 1540. Framework Adjustment 1 to the Summer Flounder, Scup, and Black Sea Bass FMP, Atlantic Mackerel, Squid, and Butterfish FMP, Bluefish FMP, and Tilefish FMP established the Mid-Atlantic RSA Program (66 FR 42156, August 10, 2001), which is codified in regulations at 50 CFR 648.21(g).

Catalog of Federal Domestic Assistance (CFDA) Number: 11.454, Unallied Management Projects.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. EST on March 3, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: To apply for this NOAA Federal Funding Opportunity, please submit applications to <http://www.grants.gov> and use the following funding opportunity number: NMFS-NEFSC-2010-2001654. Applicants who do not have Internet access may submit their application to Cheryl A. Corbett, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543.

Information Contacts: Information may be obtained from Clay Heaton,

Fishery Management Specialist, Mid-Atlantic Fishery Management Council, by phone 302-674-2331 ext. 13, or via e-mail at cheaton@mafmc.org; or Cheryl A. Corbett, Cooperative Programs Specialist, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543, or by phone at 508-495-2070, or fax at 508-495-2004, or via e-mail at cheryl.corbett@noaa.gov; or from Ryan Silva, Cooperative Research Liaison, NMFS, Northeast Regional Office, by phone 978-281-9326, or via e-mail at ryan.silva@noaa.gov.

Eligibility: 1. Eligible applicants include institutions of higher education, hospitals, other nonprofits, commercial organizations, individuals, and state, local, and Native American tribal governments. Federal agencies and institutions are not eligible to receive Federal assistance under this notice. Additionally, employees of any Federal agency or Regional Fishery Management Council are ineligible to submit an application under this program. However, Council members who are not Federal employees may submit an application. 2. DOC/NOAA supports cultural and gender diversity and encourages women and minority individuals and groups to submit applications to the RSA program. In addition, DOC/NOAA is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. DOC/NOAA encourages proposals involving any of the above institutions. 3. DOC/NOAA encourages applications from members of the fishing community and applications that involve fishing community cooperation and participation.

Cost Sharing Requirements: None required.

Intergovernmental Review: Applicants will need to determine if their state participates in the intergovernmental review process. This information can be found at the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>. This information will assist applicants in providing either a Yes or No response to Item 16 of the Application Form, SF-424, entitled "Application for Federal Assistance."

3. FY09 Hawaii Seafood Program

Summary Description: The National Marine Fisheries Service NOAA/NMFS) is soliciting competitive applications for the FY09 Hawaii Seafood Program. The Hawaii Seafood Program is designed to help strengthen and to sustain the

economic viability of Hawaii's fishing and seafood industry through activities that promote Hawaii fisheries products as high-quality and safe domestic seafood produced by a responsible and well-managed fishery. Projects may seek support for cooperative seafood safety research, technical assistance, and/or seafood education.

Funding Availability: Total funding available under this notice is anticipated to be approximately \$700,000. Actual funding availability for this program is contingent upon FY09 Congressional appropriations. Proposals in any amount may be submitted, but awards in excess of \$250,000 are unlikely. Award amounts will be determined by the proposals and available funds. There is no set minimum or maximum amount, within the available funding, for any award. There is also no limit on the number of applications that can be submitted by the same applicant; however, multiple applications submitted by the same applicant must clearly identify different projects. If an application for a financial assistance award is selected for funding, NOAA/NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. Notwithstanding verbal or written assurance that may have been received, pre-award costs are not allowed under the award unless approved by the NOAA Grants Officer.

Statutory Authority: The statutory authority for the Hawaii Seafood Program is 15 U.S.C. 713c-3(d).

Catalog of Federal Domestic Assistance (CFDA) Number: 11.452, Unallied Industry Projects.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. Hawaii Standard Time on February 13, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: Proposals should be submitted through Grants.gov. For those applicants without Internet access, proposals should be submitted to NOAA Federal Program Officer, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, Hawaii 96814.

Information Contacts: If you have any questions regarding this proposal solicitation, please contact Scott W.S. Bloom at the NOAA/NMFS Pacific

Islands Regional Office, 1601 Kapiolani Blvd., Honolulu, Hawaii 96814, by phone at 808-944-2218, or by e-mail at Scott.Bloom@noaa.gov.

Eligibility: Eligible applicants are individuals, institutions of higher education, other nonprofits, commercial organizations, international organizations, foreign governments, organizations under the jurisdiction of foreign governments, and state, local and Indian tribal governments. Federal agencies, or employees of Federal agencies, are not eligible to apply. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. The Hawaii Seafood Program encourages proposals involving any of the above institutions.

Cost Sharing Requirements: No cost sharing or matching is required under this program but is encouraged.

Intergovernmental Review: Applications under this program are subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

4. New Bedford Harbor Restoration Projects (IV)

Summary Description: The New Bedford Harbor Trustee Council (Trustee Council or Council) is responsible for restoration of natural resources injured through the release of polychlorinated biphenyls (PCBs) and other hazardous substances into the New Bedford Harbor Environment. The Council consists of the: (1) Massachusetts Executive Office of Energy and Environmental Affairs; (2) U.S. Department of Commerce, NOAA represented by the National Marine Fisheries Service; and (3) U.S. Department of the Interior represented by the U.S. Fish and Wildlife Service. Using settlement funds, the Council plans and implements projects that restore, replace or acquire the equivalent of the natural resources that have been injured. The Council intends to fund up to \$6.0 million for restoration projects addressing the natural resource injury within the New Bedford Harbor Environment. Funding will be provided through grants or cooperative agreements issued through NOAA on behalf of the Council. Approved projects that involve activities not eligible for NOAA Grants may receive funds through other Trustee agencies.

Funding Availability: This solicitation announces that funding of up to

\$6,000,000 is expected to be available for the Council's Round IV restoration projects. Based upon previous rounds, the Council anticipates that typical project awards will range from \$20,000 to \$2,000,000. There is no guarantee that sufficient funds will be available to make awards for all proposals. The number of awards to be made as a result of this solicitation will depend on the number of eligible applications received, the amount of funds requested for initiating restoration projects by the applicants, and the merit and ranking of the proposals.

Publication of this notice does not obligate NOAA to fund any specific project or obligate all or any parts of any available funds.

Statutory Authority: 16 U.S.C. 661-667e, 42 U.S.C. 9601-9626.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.463, Habitat Conservation.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. EST on February 17, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Applications that are postmarked after the deadline date and time will not be considered for funding. No facsimile or electronic mail applications will be accepted.

Address for Submitting Proposals: Electronic submission online: <http://www.grants.gov>. Paper submission: New Bedford Harbor Trustee Council, c/o National Marine Fisheries Service, 1 Blackburn Drive, Gloucester, MA 01930-2298, Attn: Jack Terrill, 978-281-9136.

Information Contacts: For further information, contact the Trustee Council Coordinator: Jack Terrill, New Bedford Harbor Trustee Council, c/o National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930-2298, telephone 978-281-9136, e-mail jack.terril@noaa.gov.

Eligibility: Eligible applicants include state, local and Indian tribal governments, institutions of higher education, other nonprofit and commercial organizations and individuals whose projects have the potential to benefit the impacted natural resources.

Applications from Federal agencies or employees of Federal agencies can be

submitted but cannot be considered for NOAA grants. Such applications may be funded through the other Trustee Council agencies. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) and the Council are strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. The Council encourages proposals involving any of the above institutions.

Cost Sharing Requirements: One way of extending the fixed amount of funds that the Council has to work with is through cost sharing (often referred to as providing matching funds). While it is not required that applications contain cost sharing, the Council strongly encourages respondents to consider cost sharing, and if it is appropriate for a project, to discuss within the application the degree to which cost sharing may be possible. If cost sharing is proposed, applicants are asked to account for both the Council and non-Council amounts. This information will allow the Council to better plan for potential funding awards and future expenditures.

Intergovernmental Review: Applications under this program are subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs. Any applicant submitting an application for funding is required to complete Item 16 on SF-424 regarding clearance by the State Single Point of Contact (SPOC) established as a result of EO 12372. To find out about and comply with a State's process under EO 12372, the names, addresses and phone numbers of participating SPOCs are listed on the Office of Management and Budget's home page at: <http://www.whitehouse.gov/omb/grants/spoc.html>.

5. Pacific Coastal Salmon Recovery Fund

Summary Description: NOAA announces the availability of Pacific Coastal Salmon Recovery Funds (PCSRF), as authorized in the Northern Boundary and Transboundary Rivers Restoration and Enhancement Fund and Southern Boundary Restoration and Enhancement Fund (16 U.S.C. 3645), to support the restoration and conservation of Pacific salmon and steelhead populations and their habitat. The program provides funding to the States of Alaska, Washington, Oregon, Idaho and California for salmon habitat restoration, salmon stock enhancement, sustainable salmon fisheries and salmon

research. It also provides funding to the Pacific Coastal tribes and the Columbia River tribes as authorized in 16 U.S.C. 3645(d)(2)(B) for salmon habitat restoration, salmon stock enhancement, salmon research and supplementation activities.

Funding Availability: Up to \$67,000,000 may be available in fiscal year (FY) 2009 for projects as authorized under 16 U.S.C. 3645(d)(2). There are no restrictions on minimum funding requests, but there is a limit of \$25,000,000 on a maximum amount requested by any recipient. Award periods may be up to a maximum of 5 years. Actual funding availability for this program is contingent upon FY 2009 Congressional appropriations.

Statutory Authority: 16 U.S.C. 3645(d)(2).

Catalog of Federal Domestic Assistance (CFDA) Number: 11.438, Pacific Coast Salmon Recovery—Pacific Salmon Treaty Program.

Application Deadline: Pre-Applications are not mandatory, but highly encouraged. They must be received no later than February 2, 2009 if the applicant expects to receive any feedback from NMFS on completeness of package and initial determination of compliance with requirements. Final Applications should be submitted via <http://www.grants.gov> and must be received no later than 11:59 p.m. PST on February 17, 2009. No facsimile or electronic mail applications will be accepted. Paper applications must be postmarked by February 17, 2009. Any application transmitted or postmarked, as the case may be, after the deadline will be considered non-responsive and will not be considered for funding in this competition. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: Applications should be submitted online through the Grants.gov Web site at <http://www.grants.gov>. If online submission is not possible, paper applications may be mailed to Barry Thom or Nicolle Hill at 7600 Sand Point Way, NE., Seattle, WA 98115-6349.

Information Contacts: For further information on PCSRF, please contact Barry Thom, NMFS Northwest Region Deputy Regional Administrator, at (503) 231-6266. Questions regarding this announcement should be directed to

Nicolle Hill, NMFS Northwest Region PCSRF Federal Program Officer, at (206) 526-4358 or Nicolle.Hill@noaa.gov.

Eligibility: Eligible state applicants are the States of Alaska, Washington, Oregon, Idaho and California. Eligible tribal applicants are any federally recognized Pacific Coastal or Columbia River tribes in Washington, Oregon, California or Idaho.

Cost Sharing Requirements: Applicants are required to match 33% of received Federal funds. Indian tribes are exempt from any cost share requirement.

Intergovernmental Review: Applications under this program from state or local governments are subject to the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs."

6. Proactive Species Conservation Program

Summary Description: The NMFS is seeking to provide federal assistance, in the form of grants or cooperative agreements, to support conservation efforts for the current list of marine and anadromous species under the Proactive Species Conservation Program. The program supports voluntary conservation efforts designed to conserve marine and anadromous species before they reach the point at which listing as threatened or endangered under the Endangered Species Act (ESA) becomes necessary. Such proactive conservation efforts can serve as an efficient, non-regulatory, and cost-effective means of managing potentially at-risk species. To raise awareness of potentially at-risk species and to foster their proactive conservation, the NMFS created a 'species of concern' list in April 2004 (69 FR 19975). 'Species of concern' are species that are potentially at risk of becoming threatened or endangered or may potentially require protections under the ESA, yet for which sufficient data are lacking. The species-of-concern status carries no procedural or regulatory protections under the ESA. The list of species of concern and descriptions of each species are available at <http://www.nmfs.noaa.gov/pr/species/concern/#list>. Under this solicitation, any state, territorial, tribal, or local entity that has authority to manage or regulate these species or activities that affect these species is eligible to apply to this grant program. This document describes how to submit proposals for funding in fiscal year (FY) 2009 and how the NMFS will determine which proposals will be funded.

Funding Availability: This solicitation announces that approximately \$200,000

may be available for distribution in FY 2009 under the PSCP; there are no restrictions on minimum or maximum funding requests. Applicants may apply for funds for up to 5 years (see below) so the total amount requested over the life of the project may be more than \$200,000, but the limit for FY 2009 should be \$200,000. Actual funding availability for this program is contingent upon Fiscal Year 2009 Congressional appropriations. Applicants are hereby given notice that funds have not yet been appropriated for this program. There is no guarantee that sufficient funds will be available to make awards for all qualified projects.

Publication of this notice does not oblige the NMFS to award any specific project or to obligate any available funds; and, if an application is selected for funding, the NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. There is also no limit on the number of applications that can be submitted by the same applicant. Multiple applications submitted by the same applicant must clearly identify distinct projects, and single applications should not include multiple, unrelated projects. Notwithstanding verbal or written assurance that may have been received, pre-award costs are not allowed under the award unless approved by the Grants Officer in accordance with 2 CFR part 225.

Statutory Authority: Authority for the Proactive Species Conservation Program is provided by the following: 16 U.S.C. 661.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.472, Unallied Science Program.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. EST on February 12, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received. Hard copy applications must be postmarked by February 12, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: Applications should be submitted online through the Grants.gov Web site at <http://grants.gov>. If online submission is not possible, paper applications may be mailed to NOAA/NMFS/Office of Protected Resources, Attn: Dwayne Meadows, NMFS Office of Protected Resources F/PR3, 1315 East-West

Highway, SSMC3, Silver Spring, MD 20910.

Information Contacts: If you have any questions regarding this proposal solicitation, please contact Dwayne Meadows at the NMFS Office of Protected Resources F/PR3, Endangered Species Division, 1315 East-West Highway, Silver Spring, MD 20910, by phone at 301-713-1401 x199, or by e-mail at Dwayne.Meadows@noaa.gov. You may also contact one of the following people in your region for further guidance: Kim Damon-Randall, Northeast Regional Office Kimberly.Damon-Randall@noaa.gov (978-281-9300 x 6535), Alex Meyer, Southeast Regional Office Alex.Meyer@noaa.gov (727-824-5312), Krista Graham, Pacific Islands Regional Office Krista.Graham@noaa.gov (808-944-2238), Melissa Neuman, Southwest Regional Office Melissa.Neuman@noaa.gov (562-980-4115), Eric Murray, Northwest Regional Office Eric.Murray@noaa.gov (503-872-2791), Brad Smith, Alaska Regional Office Brad.Smith@noaa.gov (907-271-3023).

Eligibility: Eligible applicants are U.S. state, territorial, tribal, or local governments that have regulatory or management authority over one or more SOC or activities that affect one or more SOC. A current list of SOC can be found at <http://www.nmfs.noaa.gov/pr/species/concern/#list> or obtained from the Office of Protected Resources (see section G, Agency Contacts). Applicants are not eligible to submit a proposal under this program if they are a federal employee; however, federal employees may serve as Cooperators. In addition, NMFS employees are not allowed to actively engage in the preparation of proposals or write letters of support for any application. However, if applicable, NMFS employees can write a letter verifying that they are collaborating with a particular project. NMFS contacts (see section G) are available to provide information regarding programmatic goals and objectives associated with the PSCP, other ongoing ESA programs, regional funding priorities, and, along with other Federal Program Officers, can provide information on application procedures and completion of required forms.

Cost Sharing Requirements: There are no cost-sharing or matching requirements under this solicitation.

Intergovernmental Review: Applications submitted by state and local governments are subject to the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." Any applicant submitting an application for funding is required to

complete item 16 on SF-424 regarding clearance by the State Single Point of Contact (SPOC) established as a result of EO 12372. To find out about and comply with a State's process under EO 12372, the names, addresses and phone numbers of participating SPOCs are listed in the Office of Management and Budget's home page at: <http://www.whitehouse.gov/omb/grants/spoc.html>.

National Ocean Service (NOS)

1. Coastal and Estuarine Land Conservation Program (CELCP)—FY 2010 Competition

Summary Description: The purpose of this document is to advise eligible coastal states and territories (requirements described below) that OCRM is soliciting coastal and estuarine land conservation project proposals for competitive funding under the CELCP. States and territories must have submitted to NOAA a CELCP plan on or before February 24, 2009, in order to be eligible to participate in the FY2010 funding opportunity (see Final Guidelines for Coastal and Estuarine Land Conservation Program for more information on CELCP plan requirements, available at <http://coastalmanagement.noaa.gov/land/media/CELCPfinal02Guidelines.pdf>). Funding is contingent upon the availability of FY 2010 Federal appropriations. It is anticipated that projects funded under this announcement will have a grant start date between March 1, 2010 and October 1, 2010. The program authority is 16 U.S.C. 1456d.

Funding Availability: NOAA anticipates that approximately 20-60 projects may be included on a competitively-ranked list of projects that are ready and eligible for funding in FY 2010. Funding for projects selected for the prioritized list is contingent upon availability of Federal appropriations for FY 2010. Applicants are hereby given notice that funds have not yet been appropriated for this program. The FY 2010 President's Request for the program is \$15 million. Annual appropriated funding levels for the CELCP ranged from \$8-\$50 million from FY 2002-2008. Eligible coastal states and territories may select and submit up to three projects for this competition, including subsequent phases of projects previously funded by CELCP. Applicants may include multiple parcels in a project proposal; however, please note that NOAA will evaluate project readiness and feasibility for completion within the required 18 month timeframe. For such

projects, NOAA recommends that applicants limit the scope to acquiring no more than 5 separate parcels (including parcels that would be acquired directly with CELCP funds as well as those that would be counted an in-kind match). See section III.C. for additional details. The maximum amount that may be requested for the Federal share of each project is \$3,000,000. The amount of funding per award in previous years has ranged from \$380,000 to \$3,000,000 for competitively selected projects, depending on the amount requested, size, and type of project. There is no guarantee that sufficient funds will be available to make awards for all qualified projects. Publication of this notice and the list of projects deemed ready and eligible does not obligate NOAA to award any specific project or to obligate any available funds. If a state or territory incurs any costs prior to receiving an award agreement signed by an authorized NOAA official, they do so solely at their own risk of these costs not being included under the award. In no event will NOAA or the Department of Commerce be responsible for proposal preparation or other project costs if this program fails to receive funding or is cancelled because of other agency priorities. Recipients and sub-recipients are subject to all Federal laws and agency policies, regulations, and procedures applicable to Federal financial assistance awards. NOAA is committed to continual improvement of the grants process and accelerating the award of financial assistance to qualified recipients in accordance with the recommendations of the NOAA Program Review Team. If funding is appropriated in FY 2010 for projects recommended through this competition, NOAA will request final grant applications from successful applicants as soon as feasible in order to expedite the grant process (see VI. Award Administration Information). Applicants must be in good standing with all existing NOAA grants in order to receive funds.

Statutory Authority: Authority for the CELCP is 16 U.S.C. 1456d.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.419, Coastal Zone Management Administration Awards.

Application Deadline: Applications must be received and validated by Grants.gov on or before 6 p.m. EST on March 31, 2009. Applications submitted through Grants.gov will have a date and time indication on them.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the

application. Please keep this in mind in developing your submission timeline. Hard copy applications must be received at the OCRM Office at the address listed in this announcement.

Address for Submitting Proposals: The proposal may be submitted electronically through Grants.gov online at: <http://www.grants.gov> or by mailing an original and four copies of each proposal to Attn: Elaine Vaudreuil, NOAA, Ocean and Coastal Resource Management, National Policy and Evaluation Division (N/ORM7), 1305 East-West Highway, SSMC4, Station 10657, Silver Spring, MD 20910.

Information Contacts: CELCP Program Manager: Elaine Vaudreuil Phone: (301) 713-3155 ext 103 E-mail:

Elaine.Vaudreuil@noaa.gov or Elisabeth Morgan Phone: (301) 713-3155 ext 166 E-mail: Elisabeth.Morgan@noaa.gov.

Eligibility: Only coastal states and territories with Coastal Zone Management Programs or National Estuarine Research Reserves approved under the CZMA that have submitted a draft CELCP plan to NOAA on or before February 24, 2009, are eligible to participate in the FY 2010 CELCP competition. A list of the status of each state and territory's CELCP plan including the states and territories eligible for this competition, is available at http://coastalmanagement.noaa.gov/land/media/CELCPplans_web.pdf, and will be updated as of as of February 24, 2009. The designated lead agency for implementing CELCP in each state or territory ("lead agency") is eligible to submit projects for funding under this competition. The lead agency is presumed to be the agency designated as lead for implementing the state or territory's coastal management program, as approved under the CZMA, unless otherwise designated by the Governor. A list of lead contacts for each state and territory is available on the CELCP Web site at <http://coastalmanagement.noaa.gov/land/media/celcpstateleadcontacts.pdf>. The designated lead agency may solicit, and include in their application, project proposals from additional eligible state or territorial agencies, local governments as defined at 15 CFR 24.3, or entities eligible for assistance under section 306A(e) of the CZMA (16 U.S.C. 1455a(e)), provided that each has the authority to acquire and manage land for conservation purposes. As defined at 15 CFR 24.3, local government means a county, municipality, city, town, township, local public authority (including any public and Indian housing agency under the United States Housing Act of 1937), school district, special district, intrastate district,

council of governments (whether or not incorporated as a nonprofit corporation under State law), any other regional or interstate government entity, or any agency or instrumentality of a local government. Under section 306A(e) of the CZMA, an eligible entity may be a local government, an area-wide agency designated under Chapter 41, Subchapter II, section 3334 of Title 42, a regional agency, or an interstate agency. The public agencies/entities, or types of entities, considered to be eligible within each state or territory may be identified within the state or territory's CELCP plan. A link to a list of Web sites for state or territory CELCP plans is available on the CELCP Web site at http://coastalmanagement.noaa.gov/land/media/CELCPplans_web.pdf. The lead agency will be responsible for: Ensuring that projects are consistent with land conservation priorities outlined in the state or territory's draft or approved CELCP plan; reviewing proposals for completeness; prioritizing proposals according to CELCP plan criteria; and nominating up to three proposals to the national selection process at a requested funding level not to exceed \$3 million per proposal. For selected projects, NOAA may make financial assistance awards to the lead agency, which will be responsible for ensuring that allocated funds are used for the purposes of and in a manner consistent with this program, including any funds awarded to an eligible sub-applicant. NOAA may, with concurrence of the state or territory's CELCP lead agency, make a grant directly to the identified sub-applicant in order to expedite completion of an approved project. In such cases, the sub-applicant (as the grant recipient) will be responsible for ensuring that allocated funds are used for the approved purposes and in a manner consistent with this program. Interested parties should contact the appropriate CELCP lead in each state or territory for additional information on their project solicitation process.

Cost Sharing Requirements: Federal funds awarded under this program must be matched with non-Federal funds at a ratio of 1:1, with the following exception. In accordance with 48 U.S.C. 1469a(d), the 1:1 matching requirement is waived for any project under \$200,000 for Insular Areas, defined as the jurisdictions of the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. For any project equal to or greater than \$200,000, the matching requirement would be waived for the portion under \$200,000. The 1:1

match requirement would apply to the portion equal to or above \$200,000.

Please note: Eligible applicants choosing to apply 48 U.S.C. 1469a(d) should note the use of the waiver and the total amount of funds requested to be waived in the matching funds section of the project proposal. Non-Federal matching funds may be derived from state, local, non-governmental or private sources in the form of cash or in-kind contributions. Cost-sharing requirements for the CELCP are specified in Section 2.7 of the CELCP Guidelines. Sources of matching funds must meet the eligibility criteria and ownership and stewardship conditions of the Federal share, unless specified otherwise. (Eligibility criteria, ownership and stewardship conditions are further described below in section "III.C. Other Criteria that Affect Eligibility.") The following costs may not be counted toward the non-Federal matching share:—Costs expended prior to the grant award, unless specifically allowed as "banked match" (see C.2, below), or qualified "pre-award" costs that were incurred within 90 days before the start of a grant award.—Lands or services previously used as non-Federal match. Any funds or in-kind contributions, including the value of donated lands or services, that have been previously used to satisfy the matching requirements of this program or that that have been or will be used to satisfy another Federal grant, may not be counted toward the non-Federal matching share.—Lands or services acquired with Federal funds. Unless otherwise provided by Federal law, the value of property, interests in property or services acquired with Federal funding may not be used as non-Federal match.—Cash contribution of Federal funds. Unless otherwise provided by Federal law, funding that originated from Federal sources may not be used as non-Federal match.

Intergovernmental Review: Applications under this program are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." If the state participates in this process, a list of participating states and the clearinghouse point of contacts can be found at <http://www.whitehouse.gov/omb/grants/spoc.html>.

2. Coral Reef NGO Partnership

Summary Description: The purpose of this notice is to invite Non-Governmental Organizations with non-profit 501(c)(3) status, with expertise and experience in supporting coral reef management in U.S. and associated waters to submit a multi-year proposal for establishing a partnership for up to four years with the NOAA CRCP at both a national and international level to further the conservation of coral reefs. This document describes the coral reef conservation partnership that the CRCP envisions, identifies the qualities that NOAA desires in a partner, and describes criteria under which

applications will be evaluated for funding consideration. Partnerships selected through this notice will be implemented through a multi-year cooperative agreement of up to four years in length. CRCP funding of up to \$600,000 pursuant to section 6403 of the Coral Reef Conservation Act (CRCA) (16 U.S.C. 6401 *et seq.*) is expected to be available for initiating this partnership in FY 2009. Applications must include a generalized four year work program and a more specific work plan and budget for activities to be funded in FY 2009, in conformance with the requirements in Section IV below. Annual federal CRCP funding is anticipated to increase up to \$1,000,000 for the subsequent three years of the agreement. However, annual funding levels and any increases over FY 2009 levels will be dependent upon future budgets appropriated by Congress, partnership success, and CRCP annual priorities. The CRCP requires the partnership to match NOAA cash contributions at a minimum of a 1:1 level overall, and will give priority to those partnerships that can provide cash match for project implementation funds.

Funding Availability: This solicitation announces that CRCP funding of up to \$600,000 is expected to be available for establishing this partnership with a single NGO in 2009. NOAA anticipates that the partnership award may increase up to \$1,000,000 in FY 2010, 2011, and 2012; however annual funding levels and any increases over FY 2009 levels for successful applicants will be dependent upon future budget appropriations provided by Congress, partnership success, and overall CRCP priorities. The exact amount of funds that may be awarded and specific tasks under each annual award will be determined in pre-award negotiations between the applicant and NOAA representatives. Publication of this document does not obligate NOAA to establish any specific partnership proposed or to obligate all or any parts of the available funds for partnership activities.

Statutory Authority: Authority for the NOAA Coral Reef Conservation Program is provided by Section 6403 of the Coral Reef Conservation Act of 2000 (16 U.S.C. 6401 *et seq.*).

Catalog of Federal Domestic Assistance (CFDA) Number: 11.419, Coastal Zone Management Administration Awards.

Application Deadline: Partnership applications for funding in 2009 must be received and validated by Grants.gov on or before 5 p.m. EST on February 27, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Hard copy applications must be received at the Coral Conservation Division, Office of Ocean and Coastal Resource Management 1305 East-West Highway, 11th floor, Silver Spring, MD 20910 no later than 5 p.m. EST on February 27, 2009.

Address for Submitting Proposals: Full proposals may be submitted to Bill Millhouser, OCRM/NOAA, 1305 East-West Highway, 11th floor, N/ORM-3, Silver Spring, MD 20910.

Information Contacts: Technical point of contact for this announcement is Bill Millhouser at 301-713-3155, extension 189 or e-mail at bill.millhouser@noaa.gov. FAX: 301-713-4367. Address: OCRM/NOAA, N/ORM-3, 1305 East-West Highway, Silver Spring, MD 20910; or Dana Wusinich-Mendez, 301-713-3155 extension 159, dana.wusinich-mendez@noaa.gov.

Eligibility: Eligible applicants are limited to non-profit organizations.

Cost Sharing Requirements: One of the overall principles of the CRCP and the CRCA is to provide funding to individual projects that leverage funds and other contributions from a broad public and private sector to implement locally important habitat restoration to benefit living marine resources. To this end, applicants are required to contribute a minimum 1:1 non-Federal match overall for Federal funds requested. Additionally, those organizations that propose to provide a 1:1 cash match for project implementation funds at the national or regional level (before local, project-specific contributions are included) will be likely to score higher in the evaluation of project costs. While this is not a requirement, the CRCP strongly advises applicants to leverage as much investment as possible. The match can come from a variety of public and private sources and can include in-kind goods and services. Federal funds may not be considered matching funds. Applicants are permitted to combine non-federal contributions from additional partners in order to meet the 1:1 match expected to establish a partnership, as long as the matching funds are not already being used to match other funding sources and are available within the project period stated in the application. Applicants are also permitted to apply federally negotiated indirect costs in excess of federal share limits as described in Section IV. E. 2. "Indirect Costs." Similarly, proposals that limit administrative costs to 15% will likely

score higher on this criterion. The Applicant whose proposal is selected for partnership funding will be bound by the percentage of cost sharing reflected in the award document signed by the NOAA Grants Officer. Successful applicants should be prepared to carefully document matching contributions, including the number of volunteer or community participation hours devoted to specific projects.

Intergovernmental Review: Funding applications under the Center are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

3. FY09 Bay Watershed Education and Training Program, Adult and Community Watershed Education in the Monterey Bay

Summary Description: The California B-WET Program, Adult and Community Watershed Education, is a competitively based program that supports existing environmental education programs, fosters the growth of new programs, and encourages the development of partnerships among environmental education programs throughout the Monterey Bay watershed. Funded projects provide meaningful watershed education to adults and communities. The term meaningful watershed education is defined as outcome-based programs that educate citizens about their role in protecting water quality and demonstrate behavioral changes that improve water quality and promote environmental stewardship.

Funding Availability: This solicitation announces that approximately \$200,000 may be available in FY 2009 in award amounts to be determined by the proposals and available funds. The National Marine Sanctuary Program anticipates that approximately 3-6 grants will be awarded with these funds and that typical project awards will range from \$20,000 to \$60,000. The California B-WET Program should not be considered a long-term source of funds; applicants must demonstrate how ongoing programs, once initiated, will be sustained. There is no guarantee that sufficient funds will be available to make awards for all qualified projects. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives. Publication of this notice does not obligate NOAA to award any specific project or to obligate any available funds. If applicants incur any costs prior to an award being made, they do so at their own risk of not being reimbursed by the government. Notwithstanding verbal or written assurance that may

have been received, there is no obligation on the part of NOAA to cover pre-award costs unless approved by the Grants Officer as part of the terms when the award is made.

Statutory Authority: 33 U.S.C. 893a(a).
Catalog of Federal Domestic Assistance (CFDA) Number: 11.429, Marine Sanctuary Program.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. PST on February 27, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Both hard copy and electronic proposals received after that time will not be considered for funding and will be returned to the applicant.

Address for Submitting Proposals: Hard copy proposals may be submitted to National Marine Sanctuary Program, attention Seaberry Nachbar, 299 Foam Street, Monterey, CA 93940.

Information Contacts: Please visit the National Marine Sanctuaries B-WET Web site for further information at: <http://sanctuaries.noaa.gov/BWET> or contact Seaberry Nachbar, Monterey Bay National Marine Sanctuary office, 299 Foam Street, Monterey, CA 93940, or by phone at 831-647-4204, or fax to 831-647-4250, or via Internet at seaberry.nachbar@noaa.gov.

Eligibility: Eligible applicants are institutions of higher education, nonprofit organizations, State or local government agencies, and Indian tribal governments. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that service underserved areas. The National Marine Sanctuary Program encourages proposals involving any of the above institutions.

Cost Sharing Requirements: No cost sharing is required under this program; however, the National Marine Sanctuary Program strongly encourages applicants to share as much of the costs of the award as possible. Funds from other Federal awards will not be accepted as matching funds. The nature of the contribution (cash versus in-kind) and the amount of matching funds will be taken into consideration in the review process with cash being the preferred method of contribution.

Intergovernmental Review: Applications under this program are not subject to Executive Order 12372,

Intergovernmental Review of Federal Programs.

National Weather Service (NWS)

1. Hydrologic Research

Summary Description: This program represents a NOAA/NWS effort to create a cost-effective continuum of basic and applied research through collaborative research between the Hydrology Laboratory of the NWS Office of Hydrologic Development and academic communities or other private or public agencies which have expertise in the hydrometeorologic, hydrologic, and hydraulic routing sciences, as well as those aspects of social sciences that apply to hydrologic and water resources forecasting and how information on those forecasts is distributed and assimilated by managers and the public. These activities will engage researchers and students in basic and applied research to improve the scientific understanding of river forecasting. Ultimately these efforts will improve the accuracy of forecasts and warnings of rivers and flash floods by applying scientific knowledge and information to NWS research methods and techniques, resulting in a benefit to the public.

NOAA's program is designed to complement other agency contributions to that national effort. This Program addresses two NOAA goals: (1) Understand Climate Variability and Change To Enhance Society's Ability To Plan and Respond and (2) Serve Society's Needs for Weather and Water Information. NOAA will give sole attention to individual proposals addressing the following science priority: Use of weather observations and weather and climate forecasts for the improvement of hydrologic and water resources forecasts. The Office of Hydrologic Development is interested in receiving proposals that demonstrate the use of in situ and remote sensing techniques for weather, hydrologic and water resources observations; numerical weather and climate forecasts; and coupled surface and groundwater systems, to demonstrate how the combination of those techniques could enhance hydrologic and water resources forecasts. OHD is specifically interested in the use of cost-effective observation techniques that are applicable at high spatial resolution to large areas and that, in combination with land surface models, allow the estimation of soil moisture profiles in areas subject to artificial irrigation.

Funding Availability: Because of Federal budget uncertainties, it has not been determined how much money will be available through this

announcement. It is also uncertain exactly when the funding from the Federal budget will be available. It is expected that up to two awards will be made, depending on availability of funds and quality of the proposals. Proposals in this area should assume an annual budget of no more than \$125,000 per year for a period of 2 years.

Statutory Authority: Authority for the Hydrologic Research programs is provided by the Weather Service Organic Act, 15 U.S.C. 313, and 33 U.S.C 883d.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.462, Hydrologic Research.

Application Deadline: Applications must be received and validated by Grants.gov on or before 3 p.m. EST March 3, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Both hard copy and electronic proposals received after that time will not be considered for funding and will be returned to the applicant. The submission date on proposals submitted through Grants.gov will be the time and date indicator in the Grants.gov submission. For proposals submitted by hard copy, the submission date will be the time stamp on the received documents.

Address for Submitting Proposals: Applications should be submitted through <http://www.grants.gov>. Federal agencies or non-Federal applicants without internet access must submit applications to: Pedro Restrepo, NOAA/NWS, 1325 East-West Highway, Room 8176, Silver Spring, Maryland 20910-3283. No facsimile or e-mail copies will be accepted.

Information Contacts: The point of contact is Pedro Restrepo, NOAA/NWS/W-OHD1; 1325 East-West Highway, Room 8176; Silver Spring, Maryland 20910-3283, or by phone at 301-713-0640 ext. 210, or fax to 301-713-0963, or via e-mail to Pedro.Restrepo@noaa.gov. Questions requesting clarifications on the current proposal must be made via e-mail to Pedro.Restrepo@noaa.gov. All questions and NOAA's responses will be made public by posting on the Web under the Current Announcement heading at <http://www.weather.gov/oh/src/>.

Eligibility: Eligible applicants are Federal agencies; institutions of higher education; other nonprofits; commercial organizations; foreign governments; organizations under the jurisdiction of foreign governments; international organizations; state, local and Indian tribal governments. Applications from non Federal and Federal applicants will be competed against each other.

Proposals selected for funding from non-Federal applicants will be funded through a project grant or cooperative agreement under the terms of this notice. Proposals selected for funding from NOAA scientists shall be effected by an intra agency fund transfer. Proposals selected for funding from a non NOAA Federal agency will be funded through an inter-agency transfer.

Please Note: Before non-NOAA Federal applicants may be funded, they must demonstrate that they have legal authority to receive funds from another Federal agency in excess of their appropriation. Because this announcement is not proposing to procure goods or services from applicants, the Economy Act (31 U.S.C. 1535) is not an appropriate legal basis.

Cost Sharing Requirements: A matching share is not required by this program.

Intergovernmental Review: Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

2. Remote Community Alert Systems Program 2009

Summary Description: The Remote Community Alert Systems Program 2009 represents a NOAA/NWS effort to provide for outdoor alerting technologies in remote communities effectively underserved by commercial mobile service for the purpose of enabling residents of those communities to receive emergency messages. These activities will engage the private sector, academia, and States in opportunities and technologies to further disseminate emergency messages. This program is a contributing element of the Warning, Alert, and Response Network (WARN) Act. NOAA's program is designed to complement other agency contributions to that national effort. The Federal Communications Commission has defined a "remote" area to consist of a county with a population density of 100 persons per square mile or less, based on the most recently available Census data. Also, "commercial mobile service" means those services that are required to provide E911 services in accordance with Section 20.18 of the Commission's rules. "Effectively underserved" identifies "remote communities" that do not receive "commercial mobile service" as demonstrated by coverage maps, technical analysis, field tests, or any other reasonable means.

The program priorities for this opportunity support NOAA's mission support goal of: Weather and Water—Serve Society's Needs for Weather and Water Information.

Funding Availability: The total funding amount available for proposals is anticipated to be approximately \$2,130,000. We anticipate making multiple awards, approximately 25, ranging from \$50,000 to \$250,000.

Statutory Authority: Authority for the Remote Community Alert Systems Program is provided by: 47 U.S.C. 1204.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.468, Applied Meteorological Research.

Application Deadline: Applications must be received and validated by Grants.gov on or before 5 p.m. EST March 27, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Both hard copy and electronic proposals received after that time will not be considered for funding and will be returned to the applicant. The submission date on proposals submitted through Grants.gov will be the time and date indicator in the Grants.gov submission. For proposals submitted by hard copy, the submission date will be the time stamp on the received documents. Hard copy applications must be received by NOAA/NWS no later than 5 p.m., March 27, 2009.

Address for Submitting Proposals: Proposals should be submitted through <http://www.grants.gov>. For those organizations without Internet access, proposals may be sent to Craig Hodan, NOAA/NWS, 1325 East-West Highway, Room 3348, Silver Spring, Maryland 20910, Phone: 301-713-9480 x 187, e-mail: craig.hodan@noaa.gov. E-mail and fax submissions will not be accepted.

Information Contacts: Craig Hodan, NOAA/NWS, 1325 East-West Highway, Room 3348, Silver Spring, Maryland 20910, Phone: 301-713-9480 x 187, e-mail: craig.hodan@noaa.gov.

Eligibility: Eligible applicants are State Governments, U.S. Territories or Possessions and Tribal Communities. This restriction is needed to efficiently manage the potential number of applications.

Cost Sharing Requirements: No cost sharing is required under this program.

Intergovernmental Review: Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

Office of the Under Secretary (USEC)

1. Dr. Nancy Foster Scholarship Program

Summary Description: The Dr. Nancy Foster Scholarship Program provides support for independent graduate-level studies in oceanography, marine biology or maritime archaeology (including all science, engineering, and resource

management of ocean and coastal areas), particularly to women and minorities. Individuals who have been accepted to a graduate program and are U.S. citizens may apply. Scholarship selections are based on academic excellence, letters of recommendation, research and career goals, and financial need. Applicants must have and maintain a minimum 3.0 grade point average each term cumulatively and maintain full-time student status for the duration of the appointment. Dr. Nancy Foster Scholarships may provide, subject to appropriations, yearly support of up to \$32,000 per student (a 12-month stipend of \$20,000 in addition to a tuition allowance of up to \$12,000), and up to \$20,000 support for a four to six week research collaboration at a NOAA facility. A maximum of \$84,000 may be provided to masters students (up to 2 years of support and one research collaboration opportunity) and up to \$168,000 may be provided to doctoral students (up to 4 years of support and two research collaboration opportunities).

Dr. Nancy Foster Scholarship Program recipients will travel to Silver Spring, MD, for a NOAA Orientation and to meet with National Marine Sanctuaries Program staff. Awards will include travel expenses to attend the mandatory Scholarship Program orientation. Dr. Nancy Foster Scholarship recipients will also be required to participate in a research collaboration at a NOAA facility. Master's candidates will be supported for one research collaboration opportunity and Doctoral candidates will be supported for up to two research collaboration opportunities over the duration of the scholarship. The research collaboration opportunity is designed to allow scholars to conduct their research at a NOAA facility and on NOAA mission research for four to six weeks. Support for the research opportunity may be used toward allowable travel costs such as: Travel to and from the NOAA facility, housing, and per diem while conducting research at the NOAA facility. Applicants who are awarded the Nancy Foster Scholarship will identify their research collaboration opportunity(s) topic and NOAA facility during the initial scholarship year. Additional information about the scholarship can be obtained in the full announcement text of the Federal Funding Opportunity.

Funding Availability: Subject to appropriations, approximately \$500,000 will be available for FY 2009. Up to 10 new awards may be made, based on the availability of funds. The Dr. Nancy Foster Scholarship Program provides

yearly support of up to \$32,000 per student (a 12-month stipend of \$20,000 in addition to a tuition allowance of up to \$12,000) and up to \$20,000 support for a four to six week research collaboration at a NOAA facility. A maximum of \$84,000 may be provided to masters students (up to 2 years of support and one research collaboration opportunity) and up to \$168,000 may be provided to doctoral students (up to 4 years of support and up to two research collaboration opportunities).

Travel support will also be provided to Dr. Nancy Foster Scholarship Program recipients to attend a NOAA orientation in Silver Spring, MD, where they will also meet with National Marine Sanctuaries Program leadership and staff.

Statutory Authority: 16 U.S.C. 1445c-1 and 16 U.S.C.A. 1445c.

Catalog of Federal Domestic Assistance (CFDA) Number: 11.481, Educational Partnership Program.

Application Deadline: Complete applications must be received and validated by Grants.gov on or before 5 p.m. EST March 31, 2009.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Completed applications must be received by the Program Manager between January 1, 2009, and March 31, 2009, at 5 p.m. Eastern Daylight Time, through Grants.gov.

Address for Submitting Proposals: Except for transcripts and letters of recommendation, as discussed in Sections IV.B.7. and IV.B.8. of the full Federal funding opportunity, applications must be submitted through Grants.gov. If an applicant does not have Internet access to complete the application through Grants.gov, hard copy applications may be submitted in one envelope to: Dr. Nancy Foster Scholarship Program, ATTN: Dr. Priti Brahma, NOAA Office of Education, 1315 East-West Highway, SSMC3, Room 10725, Silver Spring, MD 20910. Failure to submit all application items, except transcripts and letters of recommendation, in one envelope will result in disqualification of the application.

Information Contacts: Send requests for information to fosterscholars@noaa.gov or mail requests to Dr. Nancy Foster Scholarship Program, ATTN: Dr. Priti Brahma, Office of Education, 1315 East-West Highway, SSMC3, Room 10725, Silver Spring, MD 20910.

Eligibility: Only individuals who are United States citizens currently pursuing a masters or doctoral level degree in oceanography, marine biology

or maritime archaeology (including all science, engineering, and resource management of ocean and coastal areas) at a U.S. accredited graduate institution are eligible for an award under this scholarship program. In addition, students must have and maintain a minimum cumulative and term grade point average of 3.0 and maintain full-time student status for every term and for the duration of their award. Universities or other organizations may not apply on behalf of an individual.

Prospective scholars do not need to be enrolled, but must be admitted to a graduate level program in order to apply for this scholarship. Eligibility must be maintained for each succeeding year of support and annual reporting requirements, to be specified at a later date, will apply.

Cost Sharing Requirements: There are no matching requirements for this award.

Intergovernmental Review: Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

2. Environmental Literacy Grants: Science On a Sphere Network Capacity Building

Summary Description: The NOAA Office of Education (OEd) is issuing a request for applications for projects designed to build capacity within NOAA's Science On a Sphere (SOS) Users Collaborative Network (Network) to enhance the educational use of spherical display systems as public exhibits. There are two goals for this program: (1) To improve the understanding of how spherical display systems can be used to enhance informal science education learning, and (2) to build environmental literacy among the general public through increased use of ocean, coastal, Great Lakes, weather, and climate data in informal education institutions. This FFO meets NOAA's Mission Goal to provide Critical Support for NOAA's Mission. It is required that the Principal Investigator (PI) for any application submitted to this opportunity be affiliated with a Network member institution. Members of the Network are those institutions that have received funding from NOAA related to spherical display systems or have purchased NOAA's SOS system to display in a public education setting. More information on the Network and an up-to-date list of members is available at: <http://www.oesd.noaa.gov/network>. It is anticipated that recommendations for funding under this announcement will be made by May 29, 2009, and that

projects funded under this announcement will have a start date no earlier than August 1, 2009. Note: An MS Word-formatted version of this announcement is available at http://www.oesd.noaa.gov/funding_opps.html.

Funding Availability: NOAA anticipates the availability of approximately \$500,000 of total Federal financial assistance from FY09 and FY10 for Environmental Literacy Grants for Science On a Sphere Network Capacity Building. NOAA will only consider projects that have an award period of one to three years. The total Federal amount that may be requested from NOAA shall not exceed \$100,000 including direct and indirect costs.

Applications requesting Federal support from NOAA of more than \$100,000 total for all years of the award will not be considered for funding through this announcement. The amount of funding available through this announcement will be dependent upon the final FY09 and FY10 appropriation. Publication of this notice does not oblige DOC/NOAA to award any specific project or to obligate any available funds. If an applicant incurs any costs prior to receiving an award agreement from an authorized NOAA Grants Officer, the applicant would do so solely at one's own risk of such costs not being included under the award.

Statutory Authority: Authority for this program is provided by the following 33 U.S.C. 893a(a).

Catalog of Federal Domestic Assistance (CFDA) Number: 11.469, Congressionally Identified Awards and Projects.

Application Deadline: The deadline for applications is 5:00 p.m. e.s.t. on February 19, 2009. Applications submitted through Grants.gov will have a date and time indication on them. Hard copy applications will be date and time stamped when they are received.

Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

Address for Submitting Proposals: For non-Federal applicants, application should be submitted through grants.gov (<http://www.grants.gov>). For Federal applicants, please contact NOAA's Office of Education by contacting Carrie McDougall at Carrie.mcdougall@noaa.gov or (202) 482-0875 or John McLaughlin at john.mclaughlin@noaa.gov or (202) 482-2893 for application submission instructions. If an applicant does not have Internet access, paper applications will be accepted. Paper applications must be submitted with completed,

signed, original forms and one printed copy of the rest of the application. Applicants are also asked to provide a CD of the application, including scanned signed forms or forms with electronic signatures. Paper applications should be delivered to: Carrie McDougall, Dept. of Commerce, NOAA Office of Education, 1401 Constitution Avenue NW., Room 6863, Washington, DC 20230. See the Office of Education's frequently asked questions site http://www.oesd.noaa.gov/dataviz_faqs.html for more details. Please note: Paper applications submitted via the U.S. Postal Service can take up to 4 weeks to reach this office; therefore applicants are recommended to send paper applications via expedited shipping methods (e.g., Airborne Express, DHL, Fed Ex, UPS).

Information Contacts: Please visit the OEd Web site for further information at http://www.oesd.noaa.gov/funding_opps.html or contact Carrie McDougall at (202) 482-0875 or carrie.mcdougall@noaa.gov; or John McLaughlin at (202) 482-2893 or john.mclaughlin@noaa.gov. For those applicants without Internet access, hard copies of referenced documents may be requested from NOAA's Office of Education by contacting Carrie McDougall at (202) 482-0875 or John McLaughlin at (202) 482-2893 or sending a letter to Carrie McDougall, DOC/NOAA Office of Education, 1401 Constitution Avenue NW., Room 6863, Washington, DC 20230.

Eligibility: Eligible applicants are U.S. institutions of higher education, for-profit and non-profit organizations, and state, local, and Indian tribal governments and Federal agencies in the United States. Foreign institutions, foreign organizations and foreign government agencies are not eligible to apply. Individuals not affiliated with an eligible institution are not eligible to apply for funding under this announcement.

Please Note: Before non-NOAA Federal applicants may be funded, they must demonstrate that they have legal authority to receive funds from another Federal agency in excess of their appropriation.

Because this announcement is not proposing to procure goods or services from applicants, the Economy Act (31 U.S.C. 1535) is not an appropriate legal basis. The Department of Commerce/ National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to increasing the participation of Minority Serving Institutions (MSIs), i.e., Historically Black Colleges and Universities, Hispanic-serving institutions, Tribal

colleges and universities, Alaskan Native and Native Hawaiian institutions, and institutions that work in underserved communities. Applications are encouraged that involve any of the above types of institutions. An individual may serve as Principal Investigator (PI) on only one application through this funding opportunity. However, individuals may serve as co-PIs or key personnel on more than one application.

Cost Sharing Requirements: There are no cost-sharing requirements. Applicant resource commitment will, however, be considered in the competitive selection process (see the Federal Funding Opportunity Notice, section V.A.4. Evaluation Criteria, Project Costs).

Intergovernmental Review: Applications submitted to this funding opportunity are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

Limitation of Liability

Funding for programs listed in this notice is contingent upon the availability of Fiscal Year 2009 appropriations. Applicants are hereby given notice that funds have not yet been appropriated for the programs listed in this notice. In no event will NOAA or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige NOAA to award any specific project or to obligate any available funds.

Universal Identifier

Applicants should be aware that they are required to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number during the application process. See the October 30, 2002 **Federal Register** (67 FR 66177) for additional information. Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or via the Internet <http://www.dunandbradstreet.com>.

National Environmental Policy Act (NEPA)

NOAA must analyze the potential environmental impacts, as required by the National Environmental Policy Act (NEPA), for applicant projects or proposals which are seeking NOAA federal funding opportunities. Detailed information on NOAA compliance with NEPA can be found at the following NOAA NEPA Web site: <http://www.nepa.noaa.gov/>, including our NOAA Administrative Order 216-6 for

NEPA, <http://www.nepa.noaa.gov/NAO216-6-TOC.pdf>, NEPA Questionnaire, <http://www.nepa.noaa.gov/questionnaire.pdf>, and the Council on Environmental Quality implementation regulations, <http://ceq.eh.doe.gov/nepa/regs/ceq/toc-ceq.htm>. Consequently, as part of an applicant's package, and under their description of their program activities, applicants are required to provide detailed information on the activities to be conducted, locations, sites, species and habitat to be affected, possible construction activities, and any environmental concerns that may exist (e.g., the use and disposal of hazardous or toxic chemicals, introduction of non-indigenous species, impacts to endangered and threatened species, aquaculture projects, and impacts to coral reef systems). In addition to providing specific information that will serve as the basis for any required impact analyses, applicants may also be requested to assist NOAA in drafting an environmental assessment, if NOAA determines an assessment is required. Applicants will also be required to cooperate with NOAA in identifying feasible measures to reduce or avoid any identified adverse environmental impacts of their proposal. The failure to do so shall be grounds for not selecting an application. In some cases if additional information is required after an application is selected, funds can be withheld by the Grants Officer under a special award condition requiring the recipient to submit additional environmental compliance information sufficient to enable NOAA to make an assessment on any impacts that a project may have on the environment.

Compliance With Department of Commerce Bureau of Industry and Security Export Administration Regulations

(a) This clause applies to the extent that this financial assistance award involves access to export-controlled information or technology.

(b) In performing this financial assistance award, the recipient may gain access to export-controlled information or technology. The recipient is responsible for compliance with all applicable laws and regulations regarding export-controlled information and technology, including deemed exports. The recipient shall establish and maintain throughout performance of the financial assistance award effective export compliance procedures at non-NOAA facilities. At a minimum, these export compliance procedures must include adequate controls of physical, verbal, visual, and electronic

access to export-controlled information and technology.

(c) Definitions

(1) *Deemed export.* The Export Administration Regulations (EAR) define a deemed export as any release of technology or source code subject to the EAR to a foreign national, both in the United States and abroad. Such release is “deemed” to be an export to the home country of the foreign national. 15 CFR 734.2(b)(2)(ii).

(2) *Export-controlled information and technology.* Export-controlled information and technology is information and technology subject to the EAR (15 CFR parts 730 et seq.), implemented by the DOC Bureau of Industry and Security, or the International Traffic In Arms Regulations (ITAR) (22 CFR parts 120–130), implemented by the Department of State, respectively. This includes, but is not limited to, dual-use items, defense articles and any related assistance, services, software or technical data as defined in the EAR and ITAR.

(d) The recipient shall control access to all export-controlled information and technology that it possesses or that comes into its possession in performance of a financial assistance award, to ensure that access is restricted, or licensed, as required by applicable Federal laws, Executive Orders, and/or regulations.

(e) Nothing in the terms of this financial assistance award is intended to change, supersede, or waive any of the requirements of applicable Federal laws, Executive Orders or regulations.

(f) The recipient shall include this clause, including this paragraph (f), in all lower tier transactions (subawards, contracts, and subcontracts) under the financial assistance award that may involve access to export-controlled information technology.

NOAA Implementation of Homeland Security Presidential Directive—12

If the performance of a financial assistance award, if approved by NOAA, requires recipients to have physical

access to Federal premises for more than 180 days or access to a Federal information system, any items or services delivered under a financial assistance award shall comply with the Department of Commerce personal identity verification procedures that implement Homeland Security Presidential Directive -12, FIPS PUB 201, and the Office of Management and Budget Memorandum M-05-24. The recipient shall insert this clause in all subawards or contracts when the subaward recipient or contractor is required to have physical access to a Federally controlled facility or access to a Federal information system.

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696) are applicable to this solicitation.

Paperwork Reduction Act

This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424 and 424A, 424B, 424C, 424D, and SF-LLL has been approved by OMB under the respective control numbers 4040-0004, 0348-0044, 4040-0007, 0348-0041, 4040-0009, and 0348-0046. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

Executive Order 12866

This notice has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132 (Federalism)

It has been determined that this notice does not contain policies with

Federalism implications as that term is defined in Executive Order 13132.

Administrative Procedure Act/Regulatory Flexibility Act

Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act or any other law for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Dated: December 22, 2008.

Maureen E. Wylie,

Acting Director, Acquisition and Grants Office.

[FR Doc. E8-30851 Filed 12-31-08; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 09-05]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 09-05 with attached transmittal, and policy justification.

BILLING CODE 5001-06-M



**DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408**

DEC 09 2008

**The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501**

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 09-05, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost \$1.110 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey A. Wieringa".

**Jeffrey A. Wieringa
Vice Admiral, USN
Director**

Enclosures:

- 1. Transmittal**
- 2. Policy Justification**
- 3. Regional Balance (Classified Document Provided Under Separate Cover)**

Same ltr to:

House

**Committee on Foreign Affairs
Committee on Armed Services
Committee on Appropriations**

Senate

**Committee on Foreign Relations
Committee on Armed Services
Committee on Appropriations**

Transmittal No. 09-05**Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended**

- (i) **Prospective Purchaser:** Iraq
- (ii) **Total Estimated Value:**
- | | |
|--------------------------|------------------------|
| Major Defense Equipment* | \$.682 billion |
| Other | <u>\$.428 billion</u> |
| TOTAL | <u>\$1.110 billion</u> |
- (iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:** 400 M1126 STRYKER Infantry Carrier Vehicles (ICVs) or 400 M1117 Armored Security Vehicles (ASVs), 400 M2 HB 50 cal Browning Machine Guns, 8 Heavy Duty Recovery Trucks, spare and repair parts, support equipment, publications and technical data, personnel training and training equipment, contractor engineering and technical support services, and other related elements of logistics support.
- (iv) **Military Department:** Army (VCV)
- (v) **Prior Related Cases, if any:** none
- (vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none
- (vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:** none
- (viii) **Date Report Delivered to Congress:** DEC 09 2008

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Iraq –Light Armored Vehicles

The Government of Iraq has requested a possible sale of 400 M1126 STRYKER Infantry Carrier Vehicles (ICVs) or 400 M1117 Armored Security Vehicles (ASVs), 400 M2 HB 50 cal Browning Machine Guns, 8 Heavy Duty Recovery Trucks, spare and repair parts, support equipment, publications and technical data, personnel training and training equipment, contractor engineering and technical support services, and other related elements of logistics support. The estimated cost is \$1.110 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country. This proposed sale directly supports the Iraq government and serves the interests of the Iraqi people and the U.S.

The proposed sale of the Stryker ICVs, along with the munitions and support vehicles, will be used to develop a viable police force which will ensure that Iraq Army can sustain themselves in their efforts to bring stability to Iraq and to prevent overflow of unrest into neighboring countries.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor is General Dynamics Land Systems Defense Group in Sterling Heights, Michigan. There are no known offset agreements proposed in connection with this potential sale.

With the volume and wide range of items and equipment in this proposed sale, levels of U.S. Government and Contractor technical assistance will be required but cannot be fully defined at this time. The use of existing, deployed U.S. military personnel will be maximized.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Dated: December 22, 2008.

Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

[FR Doc. E8-31074 Filed 12-31-08; 8:45 am]

BILLING CODE 5001-06-C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 09-06]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the

requirements of section 155 of Public Law 104-164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 09-06 with attached transmittal, and policy justification.

Dated: December 22, 2008.

Patricia L. Toppings,
OSD Federal Register, Liaison Officer,
Department of Defense.

BILLING CODE 5001-06-M



**DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408**

DEC 09 2008

**The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501**

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 09-06, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost \$210 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey A. Wieringa".

**Jeffrey A. Wieringa
Vice Admiral, USN
Director**

Enclosures:

- 1. Transmittal**
- 2. Policy Justification**
- 3. Regional Balance (Classified Document Provided Under Separate Cover)**

Same ltr to:

House

**Committee on Foreign Affairs
Committee on Armed Services
Committee on Appropriations**

Senate

**Committee on Foreign Relations
Committee on Armed Services
Committee on Appropriations**

Transmittal No. 09-06

**Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended**

- (i) **Prospective Purchaser:** Iraq
- (ii) **Total Estimated Value:**
- | | |
|--------------------------|----------------------|
| Major Defense Equipment* | \$135 million |
| Other | <u>\$ 75 million</u> |
| TOTAL | \$210 million |
- (iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:** 20 T-6A Texan aircraft, 20 Global Positioning Systems (GPS) with CMA-4124 GNSSA card and Embedded GPS/Inertial Navigation System (INS) spares, ferry maintenance, tanker support, aircraft ferry services, site survey, unit level trainer, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, contractor technical and logistics personnel services, and other related elements of logistics support.
- (iv) **Military Department:** Air Force (SAD)
- (v) **Prior Related Cases, if any:** none
- (vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none
- (vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:** none
- (viii) **Date Report Delivered to Congress:** DEC 09 2008

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION**Iraq – T-6A Texan Aircraft**

The Government of Iraq has requested a possible sale of 20 T-6A Texan aircraft, 20 Global Positioning Systems (GPS) with CMA-4124 GNSSA card and Embedded GPS/Inertial Navigation System (INS) spares, ferry maintenance, tanker support, aircraft ferry services, site survey, unit level trainer, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, contractor technical and logistics personnel services, and other related elements of logistics support. The estimated cost is \$210 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country. This proposed sale directly supports the Iraq government and serves the interests of the Iraq people and the U.S., as well as offering hope for a more stable and peaceful Middle East.

The Iraq Air Force's (IAF) current trainer fleet consists of Cessna 172 Skyhawks and Cessna 208B Caravans. The IAF needs to supplement or replace its current trainer fleet with these new aircraft to modernize its air force and to facilitate its transition to the AT-6 light-attack aircraft.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be:

Hawker Beechcraft Corporation, Wichita, Kansas
Pratt & Whitney Corporation, Quebec, Canada and Bridgeport, West Virginia
Martin Baker, Middlesex, United Kingdom
Hartzel Propeller, Pique, Ohio
Canadian Marconi, Broken Arrow, Oklahoma
L-3 Vertex, Madison, Mississippi

There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips to Iraq involving U.S. Government and contractor representatives for technical reviews/support, program management, and training over a period of 10 years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

DEPARTMENT OF DEFENSE**Department of the Navy****Notice of Public Hearings for the Draft Environmental Impact Statement/Overseas Environmental Impact Statement for the Gulf of Mexico Range Complex****AGENCY:** Department of the Navy, DoD.**ACTION:** Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) as implemented by the Council on Environmental Quality Regulations (40 CFR Parts 1500–1508) and Executive Order 12114 Environmental Effects Abroad of Major Federal Actions, the Department of the Navy (Navy) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement/Overseas Environmental Impact Statement (EIS/OEIS) for public release on January 2, 2009. The National Marine Fisheries Service (NMFS) is a cooperating agency for the EIS/OEIS. The Draft EIS/OEIS evaluates the potential environmental impacts over a 10-year planning horizon associated with Navy Atlantic Fleet training; research, development, testing, and evaluation (RDT&E) activities; and associated range capabilities enhancements (including infrastructure improvements) within the existing Gulf of Mexico (GOMEX) Range Complex.

The GOMEX Range Complex geographically encompasses offshore, near-shore, and onshore Operating Areas (OPAREAs), ranges, and special use airspace (SUA). *Components of the GOMEX Range Complex encompass:* 17,440 square nautical miles (nm²) of OPAREA sea space; 20,810 nm² of SUA off the coasts of Florida, Alabama, Mississippi, Louisiana, and Texas; 12,000 nm² of military operating areas over Florida, Alabama, Mississippi, and Texas; as well as 15 nm² of inland range areas in east-central Mississippi and east-central Texas.

The Navy will conduct four public hearings to receive oral and written comments on the Draft EIS/OEIS. Federal, state, and local agencies and interested individuals are invited to be present or represented at the public hearings. This notice announces the dates and locations of the public hearings for this Draft EIS/OEIS.

DATES AND ADDRESSES: Public hearings will be held on the following dates and locations:

1. February 2, 2009 at the Bay Point Marriott, 4200 Marriott Drive, Panama City Beach, FL 32408;

2. February 3, 2009 at the New World Inn, 600 South Palafox Street, Pensacola, FL 23502;

3. February 4, 2009 at the New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130; and

4. February 6, 2009 at the Holiday Inn-Emerald Beach Hotel, 1102 South Shoreline Boulevard, Corpus Christi, TX 78401.

All meetings will start with an open house session from 5 p.m. to 7 p.m. followed by a formal public hearing presentation and public comment period from 7 p.m. to 9 p.m. The open house sessions will allow individuals to review the information presented in the GOMEX Range Complex Draft EIS/OEIS. Navy representatives will be available during the open house sessions to clarify information related to the Draft EIS/OEIS.

FOR FURTHER INFORMATION CONTACT:

Naval Facilities Engineering Command, Atlantic, 6506 Hampton Boulevard, Norfolk, VA 23508–1278, Attn: Code EV22TW (GOMEX EIS/OEIS PM), Fax: 757–322–4894 or <http://www.GOMEXRangeComplexEIS.com>.

SUPPLEMENTARY INFORMATION: A Notice of Intent to prepare the GOMEX Range Complex Draft EIS/OEIS was published in the **Federal Register** on August 31, 2007 (72 FR 50333–50335). Four public scoping meetings were held at the following dates and locations:

1. September 24, 2007 at the Gulf Coast Community College, Panama City, FL;

2. September 25, 2007 at the Pensacola Junior College (Warrington Campus), Pensacola, FL;

3. September 26, 2007 at the Alfred Bonnabel High School, Metairie, LA; and

4. September 28, 2007 at the Holiday Inn-Emerald Beach Hotel, Corpus Christi, TX.

The proposed action is to support and conduct current, emerging, and future training and RDT&E operations in the GOMEX Range Complex by maintaining baseline training and testing operations at current levels; modifying training and testing as necessary in support of the Fleet Readiness Training Plan (FRTP); and implementing enhanced range complex capabilities. The FRTP implements the Fleet Response Plan, which ensures continuous availability of agile, flexible, trained, and ready surge-capable (rapid response) forces. No major changes to GOMEX Range Complex facilities, operations, training, or RDT&E capacities over the 10-year planning period are expected from the proposed action. Rather, the proposed action will result in relatively small-

scale but critical range enhancements and changes to training and testing operations in the GOMEX Range Complex necessary for the Navy to maintain a state of military readiness commensurate with its national defense mission. The primary focus of the Draft EIS/OEIS is to address the recommended range enhancements and changes to current and future training and testing operations that have the potential to impact the environment.

The purpose for the proposed action is to: Achieve and maintain Fleet readiness using the GOMEX Range Complex to support and conduct current, emerging, and future training operations and RDT&E operations; expand warfare missions supported by the GOMEX Range Complex; and upgrade and modernize existing range capabilities to enhance and sustain Navy training and RDT&E. The need for the proposed action is to provide range capabilities for the training and equipping of combat-capable naval forces ready to deploy worldwide. In this regard, the GOMEX Range Complex furthers the Navy's execution of its Congressionally-mandated roles and responsibilities under Title 10 U.S.C. § 5062 by:

- Maintaining current levels of military readiness by training in the GOMEX Range Complex;
- Accommodating future increases in operational training tempo in the GOMEX Range Complex and supporting the rapid deployment of naval units or strike groups;
- Achieving and sustaining readiness of ships and squadrons so the Navy can quickly surge significant combat power in the event of a national crisis or contingency operation consistent with the FRTP;
- Supporting the acquisition and implementation into the Fleet of advanced military technology. The GOMEX Range Complex must adequately support the testing and training needed for new vessels, aircraft, and weapons systems; and
- Maintaining the long-term viability of the GOMEX Range Complex while protecting human health and the environment and enhancing the quality and communication capability and safety of the range complex.

Alternatives in this Draft EIS/OEIS were evaluated to ensure that they meet the purpose and the need of the proposed action, giving due consideration to range complex attributes such as the capability to support current and emerging Fleet tactical training and RDT&E requirements; the capability to support realistic, essential training at the level

and frequency sufficient to support the FRTP and the Tactical Training Theater Assessment and Planning Program; and the capability to support training requirements while following Navy Personnel Tempo of Operations guidelines. Reasonable alternatives were carried through the Draft EIS/OEIS analysis.

The Draft EIS/OEIS considers three alternatives as summarized below:

(1) *No Action Alternative*—maintains current operations to include surge consistent with the FRTP.

(2) *Alternative 1*—includes No Action Alternative plus eliminates Mine Warfare training (mine countermeasures and mine neutralization) within the GOMEX Range Complex, conducts new training associated with air-to-surface bomb training, and uses more Commercial Air Services aircraft for support of Air Intercept Control Exercise oppositional forces.

(3) *Alternative 2*—includes most elements of Alternative 1 but would implement additional enhancements to enable the GOMEX Range Complex to meet foreseeable needs. These include implementation of the Joint National Training Capability, elimination of High Explosive (HE) bomb use during major exercise air-to-surface bombing events, decreasing HE bomb use during unit level training, and increasing Non-Explosive Practice Munition (NEPM) bomb use during major exercises. Alternative 2 is considered the Preferred Alternative.

The decision to be made by the Assistant Secretary of the Navy (Installations & Environment) is to determine which alternatives analyzed in the Draft EIS/OEIS satisfy both the level and mix of training and RDT&E to be conducted and the range capabilities enhancements to be made within the GOMEX Range Complex that best meet the needs of the Navy given that all reasonably foreseeable environmental impacts have been considered.

This Draft EIS/OEIS evaluates the potential environmental effects of GOMEX Range Complex Navy Atlantic Fleet training, RDT&E activities, and associated range capabilities enhancements over a 10-year planning horizon. Alternatives are evaluated within twenty environmental resource areas according to identified stressors. The twenty environmental resource areas include, but are not limited to, water, air quality, marine communities, marine mammals, sea turtles, fish, essential fish habitat, seabirds, migratory birds, cultural, regional economy, and public health and safety. Identified stressors include, but are not limited to, vessel movements, aircraft

over flights, NEPMs, underwater detonations, and HE ordnance. The analysis includes an evaluation of the short term, long term, direct, indirect, and cumulative impacts as well as addresses methods to reduce or minimize impacts to affected resources. The analysis indicates that implementation of the No Action Alternative, Alternative 1, or Alternative 2 would not result in unavoidable significant adverse effects to resources analyzed. The analysis indicates no significant impact to resources in U.S. territorial waters and no significant harm to resources in non-territorial waters.

In accordance with 50 CFR 401.12, the Navy will prepare a biological evaluation to assess the potential effects of the proposed action on marine resources and anadromous fish protected under the Endangered Species Act (ESA). In accordance with the Marine Mammal Protection Act (16 U.S.C. 1371[a][5]), the Navy submitted a request for a Letter of Authorization for the incidental taking of marine mammals due to the proposed action. The Navy will submit a consultation package in accordance with legal requirements set forth under regulations implementing Section 7 of the ESA (50 CFR 402; 16 U.S.C 1536 (c)) for listed species under jurisdiction of the U.S. Fish and Wildlife Service and the NMFS.

The GOMEX Draft EIS/OEIS was distributed to Federal, State, and local agencies, elected officials, and other interested individuals and organizations on January 2, 2009. The public comment period will end on February 16, 2009. Copies of the GOMEX Draft EIS/OEIS are available for public review at the following libraries:

1. Bay County Public Library, 898 West 11th Street, Panama City, FL 32401;
2. Pensacola Public Library, 200 West Gregory Street, Pensacola, FL 32501;
3. West Florida Public Library—Southwest Branch, 12248 Gulf Beach Highway, Pensacola, Pensacola, FL 32507;
4. Walton County Coastal Library, 437 Greenway Trail, Santa Rosa Beach, FL 32459;
5. Meridian-Lauderdale County Public Library, 2517 Seventh Street, Meridian, MS 39301;
6. Ben May Main Library, 701 Government Street, Mobile, AL 36602;
7. East Bank Regional Library, 4747 West Napoleon Avenue, Metairie, LA 70001;
8. New Orleans Public Library—Main Library, 219 Loyola Avenue, New Orleans, LA 70112;

9. Central Library, 805 Comanche, Corpus Christi, TX 78401; and

10. Southmost Branch Library, 4320 Southmost Blvd, Southmost, TX 78522.

The GOMEX Draft EIS/OEIS is also available for electronic public viewing at <http://www.GOMEXRangeComplexEIS.com>. A paper copy of the executive summary or a single CD with the GOMEX Draft EIS/OEIS will be made available upon written request by contacting Naval Facilities Engineering Command, Atlantic Division; 6506 Hampton Blvd; Norfolk, VA 23508-1278; Attn: Code EV22TW (GOMEX EIS/OEIS PM); Fax: 757-322-4894.

Federal, State, and local agencies and interested parties are invited to be present or represented at the public hearing. Written comments can also be submitted during the open house sessions preceding the public hearings. Oral statements will be heard and transcribed by a stenographer; however, to ensure the accuracy of the record, all statements should be submitted in writing. All statements, both oral and written, will become part of the public record on the Draft EIS/OEIS and will be responded to in the Final EIS/OEIS. Equal weight will be given to both oral and written statements. In the interest of available time, and to ensure all who wish to give an oral statement have the opportunity to do so, each speaker's comments will be limited to three (3) minutes. If a long statement is to be presented, it should be summarized at the public hearing with the full text submitted either in writing at the hearing, or mailed or faxed to Naval Facilities Engineering Command, Atlantic Division; 6506 Hampton Blvd; Norfolk, VA 23508-1278; Attn: Code EV22TW (GOMEX EIS/OEIS PM), Fax: 757-322-4894. Comments may also be submitted on-line at <http://www.GOMEXRangeComplexEIS.com> during the comment period. All comments must be postmarked by February 16, 2009 to ensure they become part of the official record. All comments will be addressed in the Final EIS/OEIS.

Dated: December 22, 2008.

T. M. Cruz,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8-31232 Filed 12-31-08; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF DEFENSE**Department of the Navy****Notice of Public Hearings for the Swimmer Interdiction Security System at Naval Base Kitsap—Bangor, Kitsap County, WA Draft Environmental Impact Statement**

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 (42 United States Code [U.S.C.] 4321); the Council on Environmental Quality (CEQ) Regulations for implementing the procedural provisions of NEPA (Title 40 Code of Federal Regulations [CFR] Parts 1500–1508); Department of the Navy Procedures for Implementing NEPA (32 CFR 775); Executive Order (EO) 12114, Environmental Effects Abroad of Major Federal Actions; and Department of Defense (DoD) regulations implementing EO 12114 (32 CFR Part 187), the Department of the Navy (Navy) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement on December 17, 2008.

The DEIS evaluates the potential environmental impacts associated with construction and operation of a Swimmer Interdiction Security System at Naval Base Kitsap—Bangor (NBK—Bangor). A Notice of Intent for this Draft EIS was published in the **Federal Register** on February 12, 2007 (volume 72, number 28).

The Navy will conduct two public hearings to receive oral and written comments on the Draft EIS. Federal agencies, state agencies, Tribal Governments and local agencies and interested individuals are invited to be present or represented at the public hearings. This notice announces the dates and locations of the public hearings for this Draft EIS.

An open house session will precede the scheduled public hearing at each of the locations listed below and will allow individuals to review the information presented in the Draft EIS. Navy representatives will be available during the open house sessions to clarify information related to the Draft EIS.

DATES AND ADDRESSES: Both meetings will start with an open house session from 5 p.m. to 6:30 p.m. A presentation and formal public comment period will be held from 7 p.m. to 9 p.m. Public hearings will be held on the following dates and at the following locations:

1. February 11, 2009, Silverdale Community Center, 9729 Silverdale Way, NW, Silverdale, WA.

2. February 12, 2009, Tyee High School, 4424 S. 188th, SeaTac, WA.

FOR FURTHER INFORMATION CONTACT: Department of the Navy, SSC Pacific, 53560 Hull St., San Diego, CA, 92152, Attn: Mike Rothe Fax: 619–221–5251, e-mail: NBKEIS@spawar.navy.mil or <http://www.nbkeis.gcsaic.com>.

SUPPLEMENTARY INFORMATION: The proposed action is to install and operate a Swimmer Interdiction Security System (SISS) along the waterfront on Hood Canal at NBK-Bangor.

The purpose of the proposed action is to provide waterside security at NBK-Bangor capable of countering threats from intruders. The implemented system must be able to find, identify, and interdict surface and underwater intruders for engagement by harbor security forces. Several classified Navy instructions establish requirements for security and protection of assets at Navy bases, including NBK-Bangor. The project need is to comply with these Navy security requirements.

Three action alternatives have been identified as well as a no action alternative:

- **Marine Mammal Alternative:** This alternative would be composed of human/marine mammal teams that would support Navy operations and respond rapidly to security alerts. The system would involve stationing California sea lions, Atlantic bottlenose dolphins and human teams at the site. The animals would reside within in-water, closed circuit enclosures attached to a dock that would be connected to an existing pier at the NBK-Bangor waterfront. Upland temporary buildings would house support personnel and equipment. The Navy marine mammals would be deployed along the waterfront in conjunction with humans aboard small power boats. The marine mammals would respond to security alerts by finding, identifying, and interdicting intruder(s).

- **Sea Lions Only Alternative:** This alternative would be composed of human/sea lion teams that would support Navy operations and respond rapidly to security alerts. The system would involve stationing California sea lions and human teams at the site. Upland temporary buildings would house support personnel and equipment. The sea lions would reside within in-water, closed-circuit enclosures attached to a dock that would be connected to an existing pier at the NBK-Bangor waterfront, and would be deployed along the waterfront

in conjunction with humans aboard small power boats. The sea lions would respond to security alerts by finding, identifying, and interdicting intruder(s). This system lacks the biosonar of the dolphins and therefore this alternative would rely heavily on the initial NBK-Bangor detection and vectoring system to interdict intruders.

- **Combat Swimmers Alternative:** Combat swimmers would be stationed at an existing pier at the NBK-Bangor waterfront, and would be deployed along the waterfront aboard small power boats equipped with necessary dive support gear. Similar upland facilities would also be required. The Combat Swimmers would rely completely on the NBK-Bangor initial detection and vectoring system to arrive at a position to interdict the intruders.

- **Remote Operated Vehicle (ROV) Alternative:** ROVs would be stationed at an existing pier at the NBK-Bangor waterfront. In-water and upland facilities would be located at the same sites as the other action alternatives. ROVs would be deployed from a boat located and available for use at the waterfront and an operator would utilize sonar and bright lights on board the ROV to maneuver toward and interdict the intruder. The ROVs would rely completely on the NBK-Bangor initial detection and vectoring system to arrive at a position within range to interdict the intruders.

- **No action alternative:** Under this alternative, no SISS would be implemented. This would not meet the project purpose and need. No new facilities would be constructed. The existing initial detection and vectoring system would be used to alert for potential threats, and harbor security forces would find and attempt to apprehend intruders without the aid of an underwater interdiction system.

The Navy conducted a literature review and held discussions with subject matter experts to identify alternatives for implementing the SISS. Nine action alternatives were identified. These alternatives were evaluated to determine their ability to meet the minimum operational selection criteria. All but three were eliminated from further consideration. The Sea Lions Only alternative was added for consideration following scoping.

The Navy analyzed potential effects of its current and proposed activities on marine mammals, fish, sea turtles, marine flora and invertebrates, terrestrial wildlife, sediments and water quality, cultural resources, recreation, land and shoreline use, public health and safety, socioeconomics and environmental justice, and air quality.

No significant adverse impacts are identified for any resource area. In accordance with Section 7 of the Endangered Species Act, the Navy is seeking concurrence with NMFS and U.S. Fish and Wildlife Service (USFWS) for "may affect, not likely to adversely affect" determinations for federally listed species. The Navy is coordinating with the Washington Department of Ecology for a Coastal Consistency Determination under the Coastal Zone Management Act. Navy analysis has indicated that under the Clean Air Act requirements, no significant impacts would occur to the regional air quality, and under the Clean Water Act there would be no significant impacts to water quality. National Historic Preservation Act analysis indicated that no significant impacts to cultural resources would occur if the proposed action or alternatives were implemented. Implementation of the No Action Alternative or any of the proposed action alternatives would not disturb, adversely affect, or result in any takes of bald eagles. None of the alternatives would result in a significant adverse effect on the population of a migratory bird species.

The decision to be made by the Assistant Secretary of the Navy (Installations & Environment) is to determine which alternatives analyzed in the EIS best meet the needs of the Navy given that all reasonably foreseeable environmental impacts have been considered.

The Draft EIS was distributed to Federal, State, and local agencies, elected officials, and other interested individuals and organizations on December 24, 2008. The public comment period will end on March 1, 2009. Copies of the Draft EIS are available for public review at the following libraries:

- Aberdeen Timberland Library, 121 E. Market St., Aberdeen, WA.
- Hoodspout Timberland Library, N. 40 Schoolhouse Hill Road, Hoodspout, WA.
- Jefferson County Rural Library District, 620 Cedar Avenue, Port Hadlock, WA.
- Kitsap Regional Library, 1301 Sylvan Way, Bremerton, WA.
- North Mason Timberland Library, 23801 NE State Rt. 3, Belfair, WA.
- Ocean Shores Public Library, 573 Pt. Brown Ave. NW, Ocean Shores, WA.
- Port Townsend Public Library, 1220 Lawrence St., Port Townsend, WA.
- Poulsbo Branch Library, 700 NE Lincoln St., Poulsbo, WA.
- Seattle Central Library, 1000 Fourth Ave. Seattle, WA.

- Tacoma Main Library, 1102 Tacoma Ave. S., Tacoma, WA.
- Quinault Indian Nation Tribal Library, P.O. Box 189, Taholah, WA.
- Skokomish Tribal Center, N 80 Tribal Center Road, Shelton, WA.
- Valley View Library, 17850 Military Rd. S., SeaTac, WA.

The SISS Draft EIS is also available for electronic public viewing at: <http://www.nbkeis.gcsaic.com>. Additional information about access to the SISS DEIS is available by contacting Navy Region North West, Environmental Public Affairs Office, Attn: Sheila Murray, 1100 Hunley Road, Building 1100 Silverdale, WA, 98315, 360-396-4981.

Federal, State, and local agencies and interested parties are invited to be present or represented at the public hearing. Written comments can also be submitted during the open house sessions preceding the public hearings.

Oral statements will be heard and transcribed by a stenographer; however, to ensure the accuracy of the record, all statements should be submitted in writing. All statements, both oral and written, will become part of the public record on the Draft EIS and will be responded to in the Final EIS. Equal weight will be given to both oral and written statements. In the interest of available time, and to ensure all who wish to give an oral statement have the opportunity to do so, each speaker's comments will be limited to three (3) minutes. If a long statement is to be presented, it should be summarized at the public hearing with the full text submitted either in writing at the hearing, or mailed or faxed to Department of the Navy, SSC Pacific, 53560 Hull St., San Diego, CA 92152, Attn: Mike Rothe, Fax: 619-221-5251, e-mail: NBKEIS@spawar.navy.mil during the comment period. All written comments must be postmarked by March 1, 2009, to ensure they become part of the official record. All comments will be addressed in the Final EIS.

Dated: December 22, 2008.

T. M. Cruz,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8-31200 Filed 12-31-08; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Information on Surplus Land at a Military Installation Designated for Disposal: NASJRB Willow Grove, PA—Jacksonville Road Housing and Shenandoah Woods Housing

AGENCY: Department of the Navy, DoD.
ACTION: Notice.

SUMMARY: This notice provides information on the surplus property at Naval Air Station Joint Reserve Base (NASJRB), Willow Grove, PA—Jacksonville Road Housing and Shenandoah Woods Housing.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Kesler, Director, Base Realignment and Closure Program Management Office, 1455 Frazee Road, San Diego, CA 92108-4310, telephone: 619-532-0993 or Mr. David Drozd, Director, Base Realignment and Closure Program Management Office, Northeast, 4911 South Broad Street, Philadelphia, PA 19112-1303, telephone: 215-897-4909.

SUPPLEMENTARY INFORMATION: In 2005, NASJRB Willow Grove, PA, was designated for closure under the authority of the Defense Base Closure and Realignment Act of 1990, Public Law 101-510, as amended (the Act). Pursuant to this designation, on January 23, 2006, land and facilities at this installation were declared excess to the Department of Navy (Navy) and available to other Department of Defense components and other Federal agencies. The Navy has evaluated all timely Federal requests and has made a decision on property required by the Federal Government.

Notice of Surplus Property: Pursuant to paragraph (7)(B) of Section 2905(b) of the Act, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, the following information regarding the redevelopment authority for surplus property at NASJRB Willow Grove, PA, including Jacksonville Road Housing and Shenandoah Woods Housing is published in the **Federal Register**.

Redevelopment Authority: The local redevelopment authority for NASJRB Willow Grove, PA, is the Horsham Township Authority for NASJRB. The point of contact is Mr. Michael J. McGee, Executive Director, 1025 Horsham Road, Horsham, PA 19044, telephone: 215-643-3131.

Surplus Property Description: The following off-site housing components of NASJRB Willow Grove, known as Jacksonville Road Housing and

Shenandoah Woods Housing are surplus to the needs of the Federal Government.

Jacksonville Road Housing Area

a. *Land.* Jacksonville Road Housing consists of approximately 2.5 acres of improved fee simple land located in lower Bucks County, Warminster, PA. In general, the area will be available when the installation closes no later than September 2011.

b. *Buildings.* The following improvements, located on the above described Jacksonville Road Housing land, will also be available when the installation closes.

(1) Single-family homes (6 structures). Comments: Approximately 9,265 square feet. Three detached garage structures (shared use). Comments: Approximately 1,200 square feet.

(2) Paved areas (roads). Comments: Approximately 1,878 square yards consisting of roads and other similar pavements. Approximately 2,230 square yards consisting of other surface areas, i.e., driveways, sidewalks, etc.

Shenandoah Woods Housing Area

a. *Land.* Shenandoah Woods Housing consists of approximately 51 acres of improved and unimproved fee simple land located in lower Bucks County, Warminster, PA. In general, the area will be available when the installation closes no later than September 2011.

b. *Buildings.* The following improvements, located on the above described Shenandoah Woods Housing land, will also be available when the installation closes.

(1) Housing Quarters (40 structures). Comments: 199 townhouse units totaling approximately 337,184 square feet.

(2) Community support facilities (6 structures). Comments: Approximately 29,087 square feet. Includes recreation pavilion, ball field, mini-mart, equipment shed, etc.

(3) Paved areas (roads). Comments: Approximately 23,136 square yards consisting of roads and other similar pavements.

Redevelopment Planning: Pursuant to section 2905(b)(7)(F) of the Act, the Horsham Township Authority for NASJRB (the LRA) will conduct a community outreach effort with respect to the surplus property and will publish, within 30 days of the date of this notice, in a newspaper of general circulation in the communities within the vicinity of NASJRB Willow Grove, PA the time period during which the LRA will receive notices of interest from State and local governments, representatives of the homeless, and other interested parties. This

publication shall include the name, address and telephone number of the point of contact for the LRA who can provide information on the prescribed form and contents of the notices of interest.

Dated: December 22, 2008.

T. M. Cruz,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8-31201 Filed 12-31-08; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Record of Decision for the Introduction of the P-8A Multi-Mission Maritime Aircraft into the U.S. Navy Fleet

AGENCY: Department of the Navy, DoD.
ACTION: Notice.

SUMMARY: The Department of the Navy (Navy), after carefully weighing the operational and environmental consequences of the proposed action, announces its decision to provide facilities and functions to support homebasing twelve P-8A Fleet squadrons and one Fleet Replacement Squadron at established maritime patrol home bases. The Navy considered applicable laws, regulations, and Executive Orders, including an analysis of the environmental effects of its actions under the requirements of Executive Order 12898 (*Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations*). The proposed action will be accomplished as set out in Alternative 5, described in the Final Environmental Impact Statement (EIS) as the preferred alternative. Implementation of the preferred alternative could begin immediately.

SUPPLEMENTARY INFORMATION: The Record of Decision (ROD) has been distributed to all those individuals who requested a copy of the Final EIS and agencies and organizations that received a copy of the Final EIS. The complete text of the Navy's Record of Decision (ROD) is available for public viewing on the project Web site at <http://www.mmaeis.com> along with copies of the FEIS and supporting documents. Single copies of the ROD will be made available upon request by contacting the Commander, Naval Facilities Engineering Command Atlantic, Attn: MMA PM, 6506 Hampton Blvd. Bldg A, Norfolk, VA 23508-1278; e-mail: chris.l.harding@navy.mil.

Dated: December 23, 2008.

T. M. Cruz,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8-31202 Filed 12-31-08; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Collection Clearance Division, 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 March 3, 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 Acting Leader, 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: December 29, 2008.

James Hyler,

Acting Leader, Information Collections Clearance Division, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title: Summer Reading Program Study.

Frequency: On Occasion.

Affected Public: Individuals or household; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 11,379.

Burden Hours: 611.

Abstract: The current OMB package requests clearance for the instruments to be used in the Summer Reading Program Study (SRP). The SRP study is a project designed to test a summer reading program's impact of reducing summer reading loss, especially for struggling readers. The data collection instruments will measure the background characteristics of the sample, the level of implementation and outcomes of the summer reading program.

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 3925. 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. E8-31215 Filed 12-31-08; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement; Overview Information; Women's Educational Equity Act Program (WEEA); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2009

Catalog of Federal Domestic Assistance (CFDA) Number: 84.083A.

Note: The Department is not inviting applications under CFDA Number 84.083B (research and development grants) for FY 2009.

DATES: *Applications Available:* January 2, 2009.

Deadline for Transmittal of Applications: February 23, 2009.

Deadline for Intergovernmental Review: April 22, 2009.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the WEEA program is: (a) To promote gender equity in education in the United States; (b) to provide financial assistance to enable educational agencies and institutions to meet the requirements of title IX of the Educational Amendments of 1972 (20 U.S.C. 1681 *et seq.*); and (c) to promote equity in education for women and girls who suffer from multiple forms of discrimination based on sex, race, ethnic origin, limited English proficiency, disability, or age.

Note: Men and boys may participate in any program or activity assisted with funds under this program.

Priorities: This competition includes three absolute priorities and one competitive preference priority that are explained in the following paragraphs. These priorities are from the notice of final discretionary grant priorities for FY 2009, published in the **Federal Register** on November 21, 2008 (73 FR 70627).

Absolute Priorities: For FY 2009 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet Priority 3 and one or both of Priority 1 and Priority 2.

These priorities are:

Priority 1—Mathematics. Projects that support activities to enable students to achieve proficiency or advanced proficiency in mathematics.

Priority 2—Science. Projects that support activities to enable students to achieve proficiency or advanced proficiency in science.

Priority 3—Student Achievement Data. Projects that collect pre- and post-intervention test data to assess the effect of the projects on the academic achievement of student participants relative to appropriate comparison or control groups.

Note: All applicants must address Priority 3—Student Achievement Data. All applicants must also address either Priority 1—Mathematics or Priority 2—Science. Applicants may address both Priority 1—Mathematics and Priority 2—Science if they believe they have the capacity and personnel to successfully address both of these priorities. However, no additional points will be earned by addressing both the mathematics and science priorities.

Note: The Department suggests that applicants that are not part of a school system establish a relationship with their project's targeted school(s) to facilitate accessing the required pre- and post-intervention test data regarding proficiency and advanced proficiency.

Competitive Preference Priority: For FY 2009 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 10 points to an application, depending on how well the application meets this priority.

This priority is:

Secondary Schools. Projects that support activities and interventions aimed at improving the academic achievement of secondary school students who are at greatest risk of not meeting challenging State academic standards and not completing high school.

Program Authority: 20 U.S.C. 7283–7283g.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The notice of final discretionary grant priorities for FY 2009, published in the **Federal Register** on November 21, 2008 (73 FR 70627).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.
Estimated Available Funds: \$1,827,714.

Contingent upon the availability of funds and the quality of applications,

we may make additional awards in FY 2010 from the list of unfunded applicants from this competition.

Estimated Range of Awards:
\$125,000–\$225,000.

Estimated Average Size of Awards:
\$182,770.

Estimated Number of Awards: 10.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. *Eligible Applicants:* Public agencies; private nonprofit agencies; organizations, including community- and faith-based organizations; institutions; student groups; community groups; and individuals.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. Fax: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: <http://www.ed.gov/pubs/edpubs.html> or at its e-mail address: edpubs@inet.ed.gov.

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.083A.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the person listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We strongly encourage you to limit the application narrative (Part III) to the equivalent of no more than 25 pages using the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the

application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

3. *Submission Dates and Times:*
Applications Available: January 2, 2009.
Deadline for Transmittal of Applications: February 23, 2009.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.6. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual’s application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: April 22, 2009.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding

restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the WEEA program, CFDA Number 84.083A, must be submitted electronically using the Governmentwide Grants.gov Apply site at <http://www.Grants.gov>. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the WEEA program at www.Grants.gov. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number’s alpha suffix in your search (e.g., search for 84.083, not 84.083A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will

notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at <http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf>.

- To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see http://www.grants.gov/applicants/get_registered.jsp). These steps include (1) registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>). You also must provide on your application the same D-U-N-S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to submit successfully an application via Grants.gov. In addition, you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for

SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your

application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Beverly A. Farrar, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W242, Washington, DC 20202-5950. Fax: (202) 205-5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention:

(CFDA Number 84.083A), LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.083A), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC, time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from WEEA and 34 CFR 75.210 of EDGAR. The maximum possible score for each criterion is indicated in parentheses after each criterion. Each criterion also includes the factors that the reviewers will consider in determining how well an application meets the criterion. The maximum score for all of the criteria is 100 points. The note following selection criterion (5) is guidance to help applicants in preparing the applications and is not required by statute or regulations. The selection criteria are as follows:

(1) *Project as a component of a comprehensive plan (15 points).* The Secretary reviews each application to determine the extent to which the project is a significant component of a comprehensive plan for education equity and compliance with title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) in the particular local educational agency, institution of higher education, vocational-technical institution, or other education agency or institution.

(2) *Implementing an institutional change strategy (15 points).* The Secretary reviews each application to determine the extent to which the project would implement an institutional change strategy with long-term impact that will continue as a central activity of the applicant after the grant has been terminated.

(3) *Quality of project services (20 points).* The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Secretary considers the following factors:

(a) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services.

(b) The likelihood that the services to be provided by the proposed project will lead to improvements in the achievement of students as measured against rigorous academic standards.

(4) *Quality of the management plan (25 points).* The Secretary considers the quality of the management plan for the proposed project. In determining the

quality of the management plan for the proposed project, the Secretary considers the following factors:

(a) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, time lines, and milestones for accomplishing project tasks.

(b) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(c) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

(5) *Quality of the project evaluation (25 points).* The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(a) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(b) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings.

Note: Applicants may wish to consider using the evaluation plan to shape the development of the project from the beginning of the grant period. Applicants also may wish to include benchmarks to monitor progress toward specific project objectives and also outcome measures to assess the impact on teaching and learning or other important outcomes for project participants. Grantees will be expected to report on the progress of their evaluation through the required annual performance report as discussed in VI.3 below.

VI. Award Administration Information

1. **Award Notices:** If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. **Administrative and National Policy Requirements:** We identify administrative and national policy requirements in the application package and reference these and other

requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting*: At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. *Performance Measures*: Under the Government Performance and Results Act of 1993 (GPRA), the Secretary has established the following five performance measures for assessing the effectiveness of this program. Grantees funded under this competition will be expected to collect and report to the Department data related to these measures. Applicants should discuss in the application narrative how they propose to collect these data. These GPRA performance measures are (1) the percentage of female students served by the WEEA program who achieve proficiency on State mathematics assessments; (2) the percentage of female students served by the WEEA program who achieve advanced proficiency on State mathematics assessments; and/or (3) the percentage of female students served by the WEEA program who achieve proficiency on State science assessments; (4) the percentage of female students served by the WEEA program who achieve advanced proficiency on State science assessments; and (5) the percentage of WEEA projects whose female participants demonstrate statistically significant higher mean increases in achievement compared to mean increases of a comparison group, based on pre- and post-test data.

All applicants will be expected to collect and report data for GPRA performance measure 5. Applicants will be expected to collect and report data on measures 1 through 4 based upon the absolute priority addressed in their application and the targeted proficiency level. For example, if the applicant proposes to develop a program that

focuses on helping students achieve proficiency on State mathematics assessments, data would be collected and reported only on GPRA performance measures 1 and 5. Applicants should discuss in the application narrative how they propose to collect these data.

Notes for the GPRA measures: If the applicant uses an instrument other than assessments used for No Child Left Behind of 2001 (NCLB) purposes or for other State-level assessments, the applicant is encouraged to demonstrate that the instrument is both of the following:

(1) Valid for the subject and age range of students included in the project. Validity is the extent to which the test measures what it was supposed to (e.g. mathematics aptitude). There are several types of validity including content, construct, and predictive validity. Evidence of validity is often available from the publisher of the assessment instrument.

(2) Reliable with regard to the consistency and repeatability of measurement. Several types of reliability are routinely established, including the internal consistency of an instrument (how well different items on an instrument measure the same construct) and test/retest reliability (the consistency of measurement at two different points in time). Evidence of reliability is often available from the publisher of the assessment instrument.

Applicants should adhere to the following criteria when constructing a comparison group for reporting on the fifth GPRA measure. The comparison group should (1) match WEEA participants on a baseline measure of the achievement outcome, baseline demographics, or both; (2) be a group of no less than 20 students, and should be a group whose size is no less than 50 percent of the number of project participants; and (3) not receive WEEA project services.

For GPRA purposes, "proficiency" and "advanced proficiency" are defined as follows: (1) "Proficiency" is defined as the State standard for "proficient" for the purposes of NCLB-reporting, or its equivalent for standardized State tests; and (2) "Advanced proficiency" is defined as the State standard for "advanced proficient" for purposes of NCLB-reporting, or its equivalent for standardized State tests.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Beverly A. Farrar, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W242, Washington, DC 20202–

5950. Telephone: (202) 205–3145 or by e-mail: oiweea@ed.gov.

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: December 29, 2008.

Amanda L. Farris,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. E8–31226 Filed 12–31–08; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8589–2]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7146.

An explanation of the ratings assigned to draft Environmental Impact Statements (EISs) was published in **Federal Register** dated April 6, 2008 (73 FR 19833).

Draft EISs

EIS No. 20080360, ERP No. D-NOA-D91001-00, Amendment 1 to the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), Updating and Revising Essential Fish Habitat (EFH) for Atlantic Highly Migratory Species (HMS), consider additional Habitat Area of Particular Concern (HAPC) and Analyze Fishing Impacts, Chesapeake Bay, MD, Delaware Bay, DE, Great Bay, NJ and Outer Bank off NC

Summary: While EPA has no objection to the proposed action, it did request clarification on fishing gear impacts and monitoring plans. Rating LO.

EIS No. 20080426, ERP No. D-BLM-J01083-WY, South Gillette Area Coal Lease Applications, WYW172585, WYW173360, WYW172657, WYW161248, Proposal to Lease Four Tracts of Federal Coal Reserves, Belle Ayr, Coal Creek, Caballo, and Cordero Rojo Mines, Wyoming Powder River Basin, Campbell County, WY

Summary: EPA expressed environmental concerns about the potential for adverse impacts to air quality in the Powder River Basin. Rating EC2.

EIS No. 20080447, ERP No. D-AFS-F65072-WI, Camp Four Vegetation Project, Proposes Vegetation and Road Management Activities, Desired Future Condition (DFC), Medford-Park Falls Ranger District, Chequamegon-Nicolet National Forest, Price County, WI

Summary: EPA does not object to the preferred alternative. Rating LO.

Final EISs

EIS No. 20080423, ERP No. F-AFS-J65517-SD, West Rim Project, Proposes to Implement Multiple Resource Management Actions, Northern Hills Ranger District, Black Hills National Forest, Lawrence County, SD

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20080455, ERP No. F-AFS-J65403-00, Southern Rockies Canada Lynx Amendment, Preferred Alternative is Alternative F, Incorporating Management Direction for Canada Lynx Habitat by Amending Land and Resource Management Plans, for Arapaho-Roosevelt, Pike-San Isabel, Grand Mesa-Uncompahgre-Gunnison, San Juan, Rio Grande and Medicine Bow-Routt National Forests, Implementation, CO and WY

Summary: EPA supports the new, modified preferred alternative which should reduce potential adverse impacts to the Canada lynx. However, we have concerns that adequate resources may

not be available for monitoring and adaptive management, and continuing analysis and research regarding lynx conservation and recovery.

EIS No. 20080465, ERP No. F-AFS-J65488-WY, Battle Park Cattle and Horse (C&H) and Mistymoon Sheep and Goat (S&G) Allotment Project, Proposes to Continue Livestock Grazing on both Allotments, Powder River Ranger District, Bighorn National Forest, Bighorn County, WY

Summary: EPA continues to have concerns about the adaptive management plan and the frequency of monitoring environmental impacts.

EIS No. 20080473, ERP No. F-USN-E11064-FL, Mayport Naval Station Project, Proposed Homeporting of Additional Surface Ships, Several Permits, Mayport, FL

Summary: EPA's previous concerns have been resolved; therefore, EPA does not object to the proposed action.

Dated: December 29, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8-31216 Filed 12-31-08; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-8589-1]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-1399 or <http://www.epa.gov/compliance/nepa/>.

Weekly receipt of Environmental Impact Statements

Filed 12/22/2008 Through 12/26/2008 Pursuant to 40 CFR 1506.9.

EIS No. 20080535, Draft EIS, BLM, MT, Indian Creek Mine Expansion, Proposed Mine Expansion would include Quarry Areas, Mine Facilities, Ore Storage Sites, Soil Salvage Stockpiles, Haul Roads, and Overburden Disposal Areas, Issuing Operating Permit #00105 and Plan of Operation #MTM78300, Broadwater County, MT, *Comment Period Ends:* 03/02/2009, *Contact:* David Williams 406-533-7655.

EIS No. 20080536, Final EIS, COE, CA, Berth 97-109 (China Shipping) Container Terminal Project, Construction and Operation, Issuance of section 404 (CWA) and Section 10 Rivers and Harbor Act Permits, Port of Los Angeles, Los Angeles County, CA, *Wait Period Ends:* 02/02/2009,

Contact: Dr. Spencer D. MacNeil 805-585-2152.

EIS No. 20080537, Draft EIS, BLM, NV, Ely Energy Center, Construction and Operation 1500 MW Coal-Fired Power Plant and Associated Features, White Pine, Lincoln, Clark, Nye, Elko and Nevada Counties, NV, *Comment Period Ends:* 04/03/2009, *Contact:* Joe Incardine 801-524-3833.

EIS No. 20080538, Second Draft Supplement, NRC, VA, North Anna Power Station Unit 3, Combined License (COL) application for Construction and Operation a Based-Load Nuclear Power Plant, (NUREG-1917), in the Town of Mineral, Louisa County, VA, *Comment Period Ends:* 03/16/2009, *Contact:* Alicia Williamson 301-415-1878.

EIS No. 20080539, Draft EIS, USA, 00, Gulf of Mexico Range Complex (GOMEX), Proposed Action is to Support and Conduct Current and Emerging Training and RDT&E Operations, TX, MS, AL and FL, *Comment Period Ends:* 02/17/2009, *Contact:* Karen M. Foskey 703-602-2859.

EIS No. 20080540, Draft EIS, AFS, ID, Nez Perce National Forest (NPNF), Proposed Designated Routes and Areas for Motor Vehicle Use (DRMVU), Implementation, Idaho County, ID, *Comment Period Ends:* 02/25/2009, *Contact:* Alexandra Botello 208-983-1950.

EIS No. 20080541, Final EIS, UPS, CA, Aliso Viejo Incoming Mail Facility, Proposed Construction and Operation of a Mail Processing Facility on a 25-Acre Parcel, Aliso Viejo, Orange County, CA, *Wait Period Ends:* 02/02/2009, *Contact:* Emmy Andrews 650-615-7200.

EIS No. 20080542, Draft EIS, AFS, NV, Martin Basin Rangeland Project, Reauthorizing Grazing on Eight Existing Cattle and Horse Allotments: Bradshaw, Buffalo, Buttermilk, Granite Peak, Indian, Martin Basin, Rebel Creek, and West Side Flat Creek, Santa Rosa Ranger District, Humboldt-Toiyabe National Forest, NV, *Comment Period Ends:* 02/17/2009, *Contact:* Vern Keller 775-355-5356.

Amended Notices

EIS No. 20080523, Draft EIS, BLM, 00, UNEV Pipeline Project, Construction of a 399-mile Long Main Petroleum Products Pipeline, Salt Lake, Tooele, Juab, Millard, Iron, and Washington Counties, UT, and Lincoln and Clark Counties, NV, *Comment Period Ends:* 03/19/2009, *Contact:* Joe Incardine 801-524-3833. Revision to FR Notice

Published 12/19/2008: Correction to Title and Comment Period.

Dated: December 29, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8-31218 Filed 12-31-08; 8:45 am]

BILLING CODE 6560-50-P

Irvine, California; to acquire up to 18 percent of Heritage Bank, National Association, New York, New York.

Board of Governors of the Federal Reserve System, December 29, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8-31199 Filed 12-31-08; 8:45 am]

BILLING CODE 6210-01-S

Dated: December 29, 2008.

Russell H. Pentz,

Assistant Deputy Associate Administrator, Office of Travel, Transportation, and Asset Management.

[FR Doc. E8-31231 Filed 12-31-08; 8:45 am]

BILLING CODE 6820-14-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 January 26, 2009.

A. Federal Reserve Bank of San Francisco (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. *Carpenter Fund Manager GP, LLC, Carpenter Fund Management, LLC, Carpenter Community Bancfund, L.P., Carpenter Community Bancfund-A, L.P., Carpenter Community Bancfund-CA, L.P., CCFW, Inc., and SCJ, Inc., all of*

GENERAL SERVICES ADMINISTRATION

Federal Travel Regulation (FTR); Relocation Allowances; Notice of GSA Bulletin FTR 09-03

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Notice of a bulletin.

SUMMARY: On December 11, 2007, the General Services Administration (GSA) published FTR Amendment 2007-06 in the *Federal Register* (72 FR 70234) specifying that the Internal Revenue Service (IRS) Standard Mileage Rate for moving purposes would be the rate at which agencies will reimburse an employee for using a privately-owned vehicle for relocation on a worldwide basis. The amendment indicated that the change to the IRS Standard Mileage Rate for moving purposes applied to relocations on and after September 25, 2007, and that GSA would publish a bulletin announcing any changes to that rate made by the IRS thereafter. On November 24, 2008, the IRS announced that as of January 1, 2009, the relocation mileage rate would decrease to \$0.24 per mile for the 12 month period ending on December 31, 2009. Thus, the reimbursement rate for relocation will also be \$0.24 for the same period. GSA Bulletin FTR 09-03 may be found at <http://www.gsa.gov/federaltravelregulation>.

DATES: The bulletin announced in this notice became effective December 12, 2008, and applies to relocations performed on or after January 1, 2009 until December 31, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. Ed Davis, Office of Governmentwide Policy (M), Office of Travel, Transportation, and Asset Management (MT), General Services Administration at (202) 208-7638 or via e-mail at ed.davis@gsa.gov. Please cite FTR Bulletin 09-03.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on Draft Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda

AGENCY: Department of Health and Human Services, Office of the Secretary.
ACTION: Notice.

SUMMARY: The National Vaccine Program Office (NVPO) is soliciting public comment on the Centers for Disease Control and Prevention's Immunization Safety Office (ISO) draft Scientific Agenda related to scientific research questions in vaccine safety.

DATES: Comments on the draft ISO Scientific Agenda should be received no later than 5 p.m. on February 2, 2009.

ADDRESSES: Electronic responses are preferred and may be addressed to vaccinsafetyRFI@hhs.gov. Written responses should be addressed to National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Room 443-H, Washington, DC 20201, Attention: Vaccine Safety RFI.

FOR FURTHER INFORMATION CONTACT: Ms. Kirsten Vannice, National Vaccine Program Office, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 443-H, Washington, DC 20201; telephone (202) 690-5566; fax 202-260-1165; e-mail vaccinesafetyRFI@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Ensuring the optimal safety of vaccines and immunizations is important to everyone. NVPO is located within the Office of Public Health and Science within the Office of the Secretary, Department of Health and Human Services (HHS), and has responsibility for coordinating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities. NVAC is a statutory Federal advisory committee that provides advice and makes recommendations to the Director of the National Vaccine Program on matters related to the program.

Vaccine safety research is done from the time vaccine development begins through when it is licensed and used routinely. Within HHS, vaccine and vaccine safety research during the development process is supported primarily by the National Institutes of Health. The Food and Drug Administration then carefully reviews safety and effectiveness information in deciding whether a vaccine should be licensed. After licensure, when a vaccine is used in children, adolescents or adults, its safety is monitored and further scientific studies are done to assure that the vaccine is safe, to evaluate potential safety problems, or to identify ways that the vaccine can be used more safely.

The Center for Disease Control and Prevention's (CDC) Immunization Safety Office (ISO) has significant responsibility for monitoring and studying the safety of vaccines after they are licensed and used in the United States (<http://www.cdc.gov/vaccinesafety>). ISO has drafted a scientific agenda that identifies vaccine safety issues to consider for scientific study over the next five years, in addition to any new questions that may arise. Since not all questions and issues can be addressed at once, setting priorities is important. The draft ISO Scientific Agenda can be found at: http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf and the addendum at http://www.cdc.gov/vaccinesafety/00_pdf/draft_recommendations_add_080410.pdf.

ISO has requested a review of the draft Scientific Agenda by the National Vaccine Advisory Committee (NVAC).

The NVAC review of the draft ISO Scientific Agenda will include providing recommendations on the agenda contents and on priorities for scientific research either done or funded by ISO. Public and stakeholder input will be important to the development of the NVAC recommendations, along with the expertise of the NVAC and NVAC Vaccine Safety Working Group members. Public and stakeholder input is being requested by written comment in response to this RFI; at community meetings taking place in Ashland, OR, Birmingham, AL, and Indianapolis, IN; at a meeting of stakeholders; and at a meeting of the NVAC Vaccine Safety Working Group (for more information, see <http://www.hhs.gov/nvpo/nvac/PublicEngagement.html>).

Through this RFI, HHS is seeking comments from everyone, including stakeholders and the broad public. Comments received will be available for

public viewing and will be presented in an open meeting on February 4, 2009, to the NVAC Vaccine Safety Working Group.

II. Information Request

NVPO, on behalf of the NVAC Vaccine Safety Working Group requests input in three broad areas: (1) Concerns about vaccines and immunization safety, (2) comments on what values, considerations, or factors are most important to consider in prioritizing scientific research, and (3) specific comments on the draft ISO Scientific Agenda. Responders may address one or all of the topics below.

(1) *Concerns about vaccines and immunization safety:* What are your primary concerns about the safety of vaccines and immunization? Why are those concerns most important to you? If interested, please share any personal experience that may further explain your concerns and their importance. [Provide up to 3 pages for an answer to this question]

(2) *Comments on what values or factors are most important to consider in prioritizing scientific research:* What values, considerations, or factors are most important to you in deciding what vaccine and immunization safety research should be conducted first? Why are these values, considerations, and factors most important to you? Examples of values or factors that you may consider include, but are not limited to, the frequency, severity, or duration of an event; the age, number of people, or vulnerability of persons exposed to a vaccine; the amount of scientific or public concern; and whether or not a vaccine is required for child-care or school entry or as a condition for employment. [Provide up to 3 pages for an answer to this question]

(3) *Specific comments on the ISO draft scientific agenda:* The draft CDC ISO Scientific Agenda can be viewed and downloaded from the CDC Web site (internet address is provided in the Background section, above).

a. Please provide any general comments on the draft ISO Scientific Agenda.

b. The following questions relate to the 30 items identified as potential 5-year research needs (see page 27 of draft ISO Scientific Agenda for a condensed list):

i. What scientific issues should be included in the draft ISO Scientific Agenda that are not there now, or what issues that are currently included should be removed? Why should these issues be added or deleted?

ii. What issues in the draft ISO Scientific Agenda are most important to you and should be made a priority to study and what issues are least important to you? Why are they the highest or lowest priorities?

[Provide up to 3 pages for an answer to this question]

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and vaccine safety. Some examples of these organizations include but are not limited to the following:

- General public;
- Advocacy groups and public interest organizations;
- State and local governments;
- State and local public health departments;
- Vaccine manufacturing industry, distributors and other businesses;
- Health care professional societies and organizations.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not have their comments posted.

The submission of written materials in response to the RFI should not exceed 9 pages (3 pages for each of the three broad topics), not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

Public Access: Responses to this RFI will be available to the public on the NVAC Web site at <http://www.hhs.gov/nvpo/nvac/PublicEngagement/RFIResponses.html>. You may access public comments received from this RFI by going to the above Web site.

Dated: December 22, 2008.

Raymond A. Strikas,

Acting Director, National Vaccine Program Office, U.S. Department of Health and Human Services.

[FR Doc. E8-31196 Filed 12-31-08; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2008-D-0516]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA." This guidance document describes a means by which an enterovirus nucleic acid assay may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of the enterovirus nucleic acid assays into class II (special controls). This guidance document is immediately in effect as the special control for an enterovirus nucleic acid assay, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0725.

SUPPLEMENTARY INFORMATION:**I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of the enterovirus nucleic acid assays into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for an enterovirus nucleic acid assay device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Consistent with the statute, on March 16, 2007, FDA issued an order classifying the enterovirus nucleic acid assay into class II with special controls. Because the device has been classified into class II with the guidance document as a special control, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before implementing this guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on nucleic acid amplification assays for the detection of enterovirus RNA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1665 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts. **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520) (the PRA). The collections of information in part 807 (21 CFR part 807), subpart E including § 807.87, have been approved under OMB Control No. 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910-0078; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB Control No. 0910-0130; and the collections of information in 21 CFR 809.10 have been approved under OMB Control No. 0910-0485. In addition, FDA concludes that the labeling statement in Section 7, *Intended Use*, of the guidance does not constitute a "collection of information" under the PRA. Rather, this labeling statement is "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. 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. Revised 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>.

Dated: December 16, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8-31214 Filed 12-31-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Blood Products Advisory Committee; Notice of Meeting; Amendment

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the Blood Products Advisory Committee. This meeting was announced in the **Federal Register** of December 9, 2008 (73 FR 74725). The amendment is being made to reflect a change in the *Agenda* portion of the document.

FOR FURTHER INFORMATION CONTACT:

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HF71-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal**

Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 9, 2008, FDA announced that a meeting of the Blood Products Advisory Committee would be held on January 9, 2009. On page 74725, in the first column, in the 13th line of the *Agenda* portion of the document, after the phrase "Acid Constructs" the following has been added:

"Included in the update will be an overview of the Center of Veterinary Medicine's review of the new animal drug application pertaining to the genetically engineered animals producing milk that contains recombinant Antithrombin III and of the environmental assessment for that application."

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: December 24, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-31187 Filed 12-29-08; 11:15 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 3, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Elaine Ferguson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, email: elaine.ferguson@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22-307, prasugrel hydrochloride film coated oral tablets, 5 milligrams (mg) and 10 mg, Eli Lilly and Company, for the proposed indication for use in acute coronary syndrome.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 16, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 9, 2009. Time allotted for each presentation may be limited. If

the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 12, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 19, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-31217 Filed 12-31-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Advisory Committee on Organ Transplantation (ACOT). The ACOT was established by the Amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR Part 121) and, in accordance with Public Law 92-463, was chartered on September 1, 2000.

DATES: The agency must receive nominations on or before February 2, 2009.

ADDRESSES: All nominations should be submitted to the Executive Secretary,

Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12-105, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Secretary, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, at the above address.

FOR FURTHER INFORMATION CONTACT: Remy Aronoff, Executive Secretary, Advisory Committee on Organ Transplantation, at (301) 443-3300 or e-mail Remy.Aronoff@hrsa.hhs.gov.

SUPPLEMENTARY INFORMATION: As provided by 42 CFR 121.12 (64 FR 56661), the Secretary established the Advisory Committee on Organ Transplantation. The Committee is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The ACOT advises the Secretary, acting through the Administrator, HRSA, on all aspects of organ procurement, allocation, and transplantation, and on other such matters that the Secretary determines. One of its principal functions is to advise the Secretary on ways to maximize Federal efforts to increase living and deceased organ donation nationally. Other matters that recently have been reviewed by the ACOT include:

- Accreditation of all establishments required to be registered with the FDA as manufacturers of human cells, tissues, and cellular- and tissue-based products;
- Concerns about U.S. citizens traveling abroad in order to receive organ transplants (also known as transplant tourism);
- Collection of data on the long-term health status of living donors;
- Organ Procurement and Transplantation Network development and distribution within the transplant community of a set of practice guidelines to be followed with respect to public solicitation of organ donors, both living and deceased; and
- Standards of coverage for living donors relating to future adverse events.

The ACOT consists of up to 25 members, including the Chair. Members and Chair shall be selected by the Secretary from individuals knowledgeable in such fields as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification

and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members. To the extent practicable, Committee members should represent the minority, gender and geographic diversity of transplant candidates, transplant recipients, organ donors and family members served by the OPTN. In addition, the Director, Centers for Disease Control and Prevention; the Administrator, Centers for Medicare and Medicaid Services; the Commissioner, Food and Drug Administration; the Director, National Institutes of Health; and the Director, Agency for Healthcare Research and Quality (or the designees of such officials) serve as non-voting ex-officio members.

Specifically, HRSA is requesting nominations for voting members of the ACOT representing: Health care public policy; transplantation medicine and surgery, including pediatric and heart/lung transplantation; critical care medicine; nursing; epidemiology and applied statistics; immunology; law and bioethics; behavioral sciences; economics and econometrics; organ procurement organizations; transplant candidates/recipients; transplant/donor family members; and living donors. Nominees will be invited to serve a 4-year term beginning after July 2009.

HHS will consider nominations of all qualified individuals with a view to ensuring that the Advisory Committee includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the ACOT. Nominations shall state that the nominee is willing to serve as a member of the ACOT and appears to have no conflict of interest that would preclude the ACOT membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Committee to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would

benefit the workings of ACOT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, return address, and daytime telephone number at which the nominator can be contacted.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.

Dated: December 21, 2008.

Elizabeth M. Duke,

Administrator, HRSA.

[FR Doc. E8-31219 Filed 12-31-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Clinical Center, the National Institutes of Health will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

Proposed Collection: Title: The impact of clinical research training and medical education at the Clinical Center on physician careers in academia and

clinical research: *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will assess the value of the training programs administered by the Office of Clinical Research Training and Medical Education. The primary objective of the survey is to determine if training programs have had an impact on whether the trainees are performing clinical research, hold an academic appointment, have National Institutes of Health funding sources as well as to obtain information from the trainees as to what part of the National Institutes of Health medical education program they feel could be improved upon, the quality of the mentoring program, and how their National Institutes of Health training has contributed to their current clinical competence. *Frequency of response:* On occasion. *Affected Public:* Physicians, dentists, medical students, dental students, nurses, and PhDs. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Doctoral Level	625	1	0.5	312.5
Students	100	1	0.5	50
Nurses	100	1	0.5	50
Total	362.5

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of

the data collection plans and instruments, contact Linda Wisniewski, Nurse Consultant, Office of Clinical Research Training and Medical Education, CC, NIH, Building 10, Room 1N252B, 9000 Rockville Pike, Bethesda, MD 20892 or 301-496-9425 or e-mail your request, including your address to: wisniewskil@cc.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: December 24, 2008.

Laura Lee,

Project Clearance Liaison, Warren Grant Magnuson Clinical Center, National Institutes of Health.

[FR Doc. E8-31240 Filed 12-31-08; 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.

Novel Inhibitor of NF-kappa B Pathway

Description of Technology: Many tumors and blood cell cancers show overactivation of the NF-kappa B signal transduction pathway. This overactivation is associated with cancer forming in the colon, liver and other epithelial sites. In addition, there is evidence that overactivation leads to tumor formation and metastasis. However, this pathway is key for normal immunity, so any inhibition of NF-kappa B overactivation must avoid diminishing the body's ability to fight infection.

This invention claims a compound that inhibits NF-kappa B activation without affecting other transcription factors such as AP-1 and SRE binding proteins. It appears to function by blocking IKK beta and is effective at low micromolar concentrations without affecting cell proliferation or cell survival. At this low concentration, NF-kappa B is reduced to basal levels so this novel compound has prospects for preventing or treating cancer without being detrimental to immunity. In addition, because NF-kappa B overactivation contributes to a variety of inflammatory disorders including colitis, diabetes, prostatitis, and pancreatitis this compound has therapeutic applications beyond cancer.

Applications:

- Therapeutic for the chemoprevention or treatment of cancers associated with the overactivation of NF-kappa B signaling pathway.

- Therapeutic for the treatment of inflammatory disorders related to NF-kappa B overactivation.

- Reagent for the diagnosis of conditions related to overexpression of NF-kappa B.

Advantages:

- Highly specific inhibitor that allows targeting NF-kappa B without inhibiting other transcription factors.

- Effective at preventing carcinogenesis without affecting normal cell proliferation and survival.

- Therapeutic for treatment of cancer that will not compromise the immune system.

Development Status:

Market: Cancer is the second leading cause of death in the U.S. and it is estimated that 1.4 million Americans develop cancer in a year.

Inventors: Curtis J. Henrich *et al.* (NCI).

Publications: None related to invention have been published.

Patent Status: U.S. Provisional Application No. 61/098,977 filed 22 Sep 2008 (HHS Reference No. E-295-2008/0-US-01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Sabarni K. Chatterjee, Ph.D.; 301-435-5587; chatterjeesa@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute (SAIC-Frederick) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize around development of analogs and/or further investigations of mechanism of action of the compound. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Method for Predicting and Detecting Tumor Metastasis

Description of Technology: Detecting cancer prior to metastasis greatly increases the efficacy of treatment and the chances of patient survival. Although numerous biomarkers have been reported to identify aggressive tumor types and predict prognosis, each biomarker is specific for a particular type of cancer, and no universal marker that can predict metastasis in a number of cancers have been identified. In addition, due to a lack of reliability, several markers are typically required to determine the prognosis and course of therapy.

The inventors discovered a novel CPE splice variant designated CPE-Δ N and found its expression levels increase according to the presence of cancer and metastasis wherein this variant is upregulated in tumors and further increased in metastatic cancer. This data has been demonstrated both in vitro and in vivo experiments and in liver, breast, prostate, colon, and head and neck cancers. Metastatic liver cells treated with CPE-Δ N siRNA reversed the cells from being metastatic and arrested cells from further metastasis. Thus, this novel CPE isoform is a biomarker for predicting metastasis and its inhibitors have an enormous potential to increase patient survival.

Applications:

- Method to prognose multiple types of cancer and determine likelihood of metastasis.

- Method to prevent and treat cancer with CPE inhibitors.

- Method to determine the stage of cancer development.

- CPE-Δ N pharmaceutical compositions.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

- Global cancer market is worth more than eight percent of total global pharmaceutical sales.

- Cancer industry is predicted to expand to \$85.3 billion by 2010.

Inventors: Y. Peng Loh *et al.* (NICHD).
Patent Status: U.S. Provisional Application No. 61/080,508 filed 14 Jul 2008 (HHS Reference No. E-234-2008/0-US-01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301-435-4633; wongje@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Development Neurobiology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Method for Predicting and Detecting Tumor Metastasis. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: December 23, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8-31238 Filed 12-31-08; 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.

Knockout of Aryl Hydrocarbon Receptor (AhR) and Its Binding Partner Aryl Hydrocarbon Receptor Nuclear Translocator (Arnt) Each in Separate Mouse Models

Description of Technology: The technology relates to two separate knockout mouse models of related transcription factors that bind each other. The aryl hydrocarbon receptor (AhR) and the aryl hydrocarbon receptor nuclear translocator (Arnt) protein are transcription factors that play an important role in mediating the effects of man-made environmental toxins. They also play a role in mammalian homeostasis and physiological homeostasis. Members of the PAS domain/bHLH family of transcription factors, they are obligate dimerization partners with each other and other members of this family, such as hypoxia-inducible factor 1alpha (HIF1alpha). These transcription factors have been shown to be important in a number of specific tissues including ovary, vascular endothelium, keratinocytes, T-cells, and liver.

Available for licensing is a knockout mouse line in which the AhR receptor has been knocked-out, and a mouse line containing a floxed allele of the Arnt gene. The Arnt mouse line can be used to disrupt the Arnt gene in different tissues by breeding the Arnt-floxed mice with transgenic mice in which the Cre recombinase is under the control of tissue-specific promoters. These mice may be used as a research tool for drug development where PAS/bHLH transcription factors are targeted.

Applications:

- Tool for drug studies targeting PAS/bHLH transcription factors.
- Tool to probe the role of the Arnt protein in a tissue-specific manner.

Inventors: Frank J. Gonzalez and Pedro M. Fernandez-Salguero (NCI).

Related Publications:

1. S Tomita, CJ Sinal, SH Yim, and FJ Gonzalez. Conditional disruption of the aryl hydrocarbon receptor nuclear translocator (Arnt) gene leads to loss of target gene induction by the aryl hydrocarbon receptor and hypoxia-inducible factor 1alpha. *Mol Endocrinol.* 2000 Oct;14(10):1674-1681.
2. SH Yim, Y Shah, S Tomita, HD Morris, O Gavrilova, G Lambert, JM Ward, and FJ Gonzalez. Disruption of

the Arnt gene in endothelial cells causes hepatic vascular defects and partial embryonic lethality in mice. *Hepatology.* 2006 Sep;44(3):550-560.

3. P Fernandez-Salguero *et al.* Immune system impairment and hepatic fibrosis in mice lacking the dioxin-binding Ah receptor. *Science* 1995 May 5;268(5211):722-726.

Patent Status: HHS Reference Nos. E-046-2009/0 and E-047-2007/0—Research Tools. Patent protection is not being pursued for these technologies.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301-435-4074; ssstand@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Metabolism, Center for Cancer Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Recombineering Vector

Description of Technology: Transgenic mouse models have become a common experimental tool for unraveling gene function. Bacterial artificial chromosome (BAC) mediated transgenesis has proven to be a highly reliable way to obtain accurate transgene expression for *in vivo* studies of gene expression and function. A rate-limiting step in characterizing large numbers of genes by this approach has been the speed and ease by which BACs can be modified. NIH investigators have developed a highly efficient recombineering vector that can be used for modifying BACs in bacteria. This new vector contains tetracycline and chloramphenicol resistance as well as the *ccdB* gene that encodes a protein that interferes with *E. coli* DNA gyrase. This vector can be propagated in *ccdB* resistant *E. coli* strains but not in other strains (DH5a, Top10, DH10B, etc.) unless the *ccdB* is replaced by DNA inserts flanked by attB1 and attB2 sites. This vector was generated to modify BAC plasmids by RecA-mediated recombination.

The vector disclosed here bypasses the rate-limiting step in recombineering protocols; the efficient cloning of a modifying vector. It is well suited for efficient production of engineered BACs for use in a variety of *in vivo* studies.

Applications:

- The fusion of fluorescent protein or cre recombinase genes to a gene of interest.

- Generation of dominant negative mutations.

- Introduction of gene mutations that would mimic disease conditions.

- Insertion of lox sites for conditional deletion of transgenes.

- Generation of knock-out or knock-in constructs.

Inventors: Rafael C. Casellas and Susan E. Lim (NIAMS).

Patent Status: HHS Reference No. E-026-2009/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for Biological Material Licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D.; 301-435-5020; vepas@mail.nih.gov.

Collaborative Research Opportunity: The NIAMS/NIH Genomics and Immunity group is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the engineering of mouse transgenic constructs using the new vector and BAC recombineering. Please contact Rafael Casellas, Ph.D. at 301-402-7858 or e-mail to casellar@mail.nih.gov for more information.

Dated: December 22, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8-31239 Filed 12-31-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2008-0017]

Voluntary Private Sector Accreditation and Certification Preparedness Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Public meeting notice.

SUMMARY: This notice announces the date, time, location, and discussion topics for a stakeholder meeting open to the public to engage in dialogue with Department of Homeland Security (DHS) leadership and program managers regarding the Voluntary Private Sector Preparedness Accreditation and Certification Program (PS-Prep).

DATES: Tuesday, January 13, 2009, 9 a.m.–2:30 p.m.

ADDRESSES: The meeting will be held at the U.S. Chamber of Commerce, 1615 H Street, NW., Washington, DC 20062.

Instructions: Any stakeholder or member of the public who wishes to attend the public meeting or make a presentation is requested to provide his or her name and contact details, to include e-mail address and telephone number, no later than 5 p.m. Eastern Standard Time, Friday, January 9, 2009 via e-mail to the PS-Prep Program at privatesectorpreparedness@hsi.dhs.gov, or via telephone at (703) 416-8407. Everyone who plans to attend the meeting is respectfully requested to be present and seated by 8:45 a.m. Persons with disabilities who require special assistance should indicate this in their admittance request and are encouraged to identify anticipated special needs as early as possible. Although every effort will be made to accommodate all members of the public, seating is limited and will be allocated on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Grant, Incident Management Systems Integration Division, National Preparedness Directorate, National Integration Center, 500 C Street, SW., Washington, DC 20472. Phone: 202-646-3850 or e-mail: FEMA-NIMS@dhs.gov.

SUPPLEMENTARY INFORMATION: On December 24, 2008, the Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS), published a notice “Voluntary Private Sector Accreditation and Certification Preparedness Program,” announcing PS-PREP, a DHS

program established under the authority of Title IX of the 9/11 Recommendations Act, Public Law 110-53, 121 Stat. 266, 338 (Aug. 3, 2007) (9/11 Recommendations Act). See 73 FR 79140; also available at <http://www.regulations.gov/search/index.jsp>. As discussed in the notice, DHS is developing PS-PREP to raise the level of private sector preparedness through a number of means, including: (i) Establishing a system for DHS to adopt private sector preparedness standards; (ii) encouraging creation of those standards; (iii) developing a method for a private sector entity to obtain a certification of conformity with a particular DHS-adopted private sector standard, and encouraging such certification; and (iv) making preparedness standards adopted by DHS more widely available.

The December 24 notice seeks recommendations from private sector stakeholders and the public at large regarding the private sector standards that DHS should adopt, both initially and over time. 73 FR at 79142. The December 24 notice also states that DHS intends to hold two public meetings in Washington, DC to provide a forum for public comment. 73 FR at 79145.

This notice announces the first of those meetings. FEMA is hosting a public meeting to discuss issues of interest pertaining to the PS-Prep Program. The purpose of this meeting is to provide an open forum for additional comment and dialogue with DHS on the PS-Prep Program. Individuals desiring to participate will have the opportunity to make a brief, formal or informal, presentation of not more than 10 minutes and then, if desired, engage in a questions and answers session with

DHS staff responsible for implementing the PS-Prep Program. The specific issues to be discussed at this meeting will follow the information requested in the December 24 notice: Adoption of private sector preparedness standards; comments regarding a maturity model process improvement approach; small business participation and concerns; comments regarding the business case; and comments regarding the accreditation process and certification process.

Public attendance is encouraged. This will assist with the preparation of meeting materials and seating arrangements.

Dennis R. Schrader,
Deputy Administrator, National Preparedness Directorate, Federal Emergency Management Agency.

[FR Doc. E8-31155 Filed 12-31-08; 8:45 am]

BILLING CODE 9110-10-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Revocation of Customs Broker License

AGENCY: U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs Regulations (19 CFR 111.51), the following Customs broker license is canceled with prejudice.

Name	License No.	Issuing port
Miguel A. Delgado	11634	Miami.

Dated: December 22, 2008.

Daniel Baldwin,

Assistant Commissioner, Office of International Trade.

[FR Doc. E8-31230 Filed 12-31-08; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-040-07-5101-ER-F164; N-82076; 8-08807; TAS: 14X5017]

Notice of Availability of the Ely Energy Center Draft Environmental Impact Statement, White Pine County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA) 42 U.S.C. 4321 *et seq.*, the

Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (Draft EIS) for rights-of-way applications for the Ely Energy Center (EEC), a coal-fired electricity generating power plant and associated facilities north of Ely, Nevada, in White Pine County.

DATES: Written comments on the EEC Draft EIS must be received by the BLM within 90 days following the date the Environmental Protection Agency publishes the Notice of Availability in the **Federal Register**. Public meetings will be held in Las Vegas, Ely, Elko and Reno, Nevada. The date, time, and

location of the meetings will be made available at least 15 days before each meeting through public notices, media news releases, and/or mailings.

ADDRESSES: Written comments should be addressed to: EEC Project Manager, BLM Ely District Office, HC 33 Box 33500, Ely, NV 89301-9408, or sent by e-mail to EEC_DEIS@blm.gov.

Copies of the EEC DEIS are available in the Ely District Office and may also be reviewed or downloaded at: http://www.blm.gov/nv/st/en/fo/ely_field_office. In addition, the Draft EIS and associated documents will be available for review at the following locations: University of Nevada-Reno, Getchell Library, Government Publication Dept., Reno, Nevada; Washoe County Library, 301 South Center Street, Reno, Nevada; White Pine County Library, 950 Campton Street, Ely, Nevada; Clark County Library, 1401 E. Flamingo Rd., Las Vegas, Nevada.

A limited number of copies of the document will be available at the following BLM offices: Ely District Office, 702 North Industrial Way, Ely, Nevada; Elko District Office, 3900 Idaho Street, Elko, Nevada; Southern Nevada District Office, 4701 North Torrey Pines, Las Vegas, Nevada; Nevada State Office, 1340 Financial Boulevard, Reno, Nevada; Bureau of Land Management, 18th and C Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Joe Incardine, 801-524-3833.

SUPPLEMENTARY INFORMATION: The proposed Ely Energy Center is a 1,500 megawatt (MW) coal-fired power plant that would be located north of McGill, Nevada, at one of two alternative sites. The primary purposes of the EEC and related transmission interconnections is to provide company-generated, base-load electricity for Sierra Pacific Power Company and Nevada Power customers and to connect their electric systems in northern and southern Nevada, allowing the power generated by the EEC to be transported throughout the state. Sierra Pacific Power Company applied for rights-of-way (ROWs) in accordance with Title V of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1761) and the regulations under 43 CFR 2800, with the BLM for the following features: A coal-fired power plant site, transmission lines and substations, a well field and water line, rail line, and access roads. The BLM action is to consider issuing ROWs for the construction of the power plant and for the construction and operation of the ancillary facilities. Also, as provided for in Decision LR 21 of the Ely Resource Management Plan,

the BLM would dispose of the power plant site to Sierra Pacific Power Company.

The BLM issued the *Notice of Intent to Prepare an Environmental Impact Statement for a Proposed Coal-Fired Electric Power Plant; Nevada*, in the **Federal Register** on January 26, 2007, with a 60-day public scoping period. Five public scoping meetings were held in February 2006. Issues identified from scoping comments include air quality impacts, emissions of greenhouse gases and impacts from water drawdown resulting from operation of the plant. Issues identified in scoping comments have been addressed in the Draft EIS.

There are three alternatives analyzed in the Draft EIS: The Proposed Action; Alternative 1, which relocates the plant to a site further to the north; and No Action.

The EEC would consist of two coal-fired 750-MW (nominal) supercritical steam turbine units using hybrid cooling systems with an expected commercial life of 50 years or longer. Water for cooling and other purposes would be obtained from a well field in the Steptoe Valley Hydrographic Basin and brought by pipeline to the plant site. Coal would be transported from the Powder River Basin in Wyoming via rail along the existing Northern Nevada Railroad or a new line running south from the Shafter, Nevada, siding for up to 100 miles (less for the northern site) of the Union Pacific east-west line. Two new 500-kV electric power transmission lines, each up to 270 miles in length, would provide a north-south interconnection to supply demand centers for Nevada consumers and tie into the EEC. The specific facilities would include the two new 500-kV power lines, expansion of the existing 500-kV Harry Allen Switching Station, and either one new 500-kV switching station at the EEC and expansion of the 500/345 kV Robinson Summit switching station, or one new 500/345-kV switching station at the EEC site.

Public comments and information submitted including names, street addresses, and e-mail addresses of respondents will be available for public review and disclosure at the above address during regular business hours (7:30 a.m. to 4:30 p.m.), Monday through Friday, except holidays. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2800.

John F. Ruhs,

Ely District Manager.

[FR Doc. E8-31220 Filed 12-31-08; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-933-1430-01; DK-G08-0001; IDI-04790, IDI-15482]

Public Land Order No. 7722; Revocation of Secretarial Order dated October 29, 1908, and Partial Revocation of Public Land Order No. 1703; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes in its entirety a Secretarial Order insofar as it affects 135.20 acres of National Forest System land within the Kaniksu National Forest withdrawn from surface entry and mining and reserved for use of the Forest Service for the Ethel Ranger Station. This order partially revokes Public Land Order No. 1703 insofar as it affects a 0.64 acre parcel of National Forest System land reserved for use by the United States Army Corps of Engineers for flood control purposes in connection with the Albeni Falls Project. This order also opens 80.64 acres of the lands to surface entry. The remaining lands will remain closed to surface entry and mining due to an overlapping withdrawal.

DATES: *Effective Date:* February 2, 2009.

FOR FURTHER INFORMATION CONTACT: Jackie Simmons, BLM Idaho State Office, 1387 S. Vinnell Way, Boise, Idaho 83709, 208-373-3867.

SUPPLEMENTARY INFORMATION: The revocation is needed to facilitate a Forest Service land conveyance pursuant to the United States Forest Service's Small Tracts Act (16 U.S.C. 1185 (2000)).

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

1. The Secretarial Order dated October 29, 1908, which withdrew National Forest System lands for the Ethel Ranger Station, is hereby revoked in its entirety as to the following described lands:

Boise Meridian

Kaniksu National Forest

T. 54 N., R. 1 W.,
Sec. 10, lot 2, S $\frac{1}{2}$ NE $\frac{1}{4}$.

The area described contains 135.20 acres in Bonner County.

2. Public Land Order No. 1703, which withdrew National Forest System lands from surface entry and mining and reserved them for use of the United States Army Corps of Engineers for flood control purposes in connection with the Albeni Falls Project, is hereby revoked insofar as it affects the following described lands:

Boise Meridian

T. 54 N., R. 1 W.,

Sec. 10, lot 2, that portion commencing in the center of Section 10 at a found 2 $\frac{1}{2}$ inches and 30 inches long aluminum pipe with a standard 3 $\frac{1}{4}$ inch aluminum cap set by Bureau of Land Management (BLM) and being buried 10 inches below the surface of road 278, to which a tamarack marked "C $\frac{1}{4}$ S10 BT" and having a diameter of 15 inches bears north 64° 3/4' east and a distance of 41.6 feet, also to which a lodgepole pine marked "C $\frac{1}{4}$ S10 B 10" and have a diameter of 17 inches bears south 44° west and a distance of 33.7 feet; thence south 89° 48' west, a distance of 649.8 feet (9.83 chains) along the east-west centerline of said Section 10 to the northeast corner of government lot 5 and a found 2 $\frac{1}{2}$ inches and 30 inches long aluminum pipe with a standard 3 $\frac{1}{4}$ inch aluminum cap set by BLM, said corner of government lot 5 also being the POINT OF BEGINNING and the southwest corner of subject property; thence north a distance of 65.0 feet to the northwest corner of subject property and a set 3/4 inch and 24 inches long rebar with a 3 $\frac{3}{4}$ inch aluminum cap; thence north 89° 48' east, a distance of 431.8 feet to the northeast corner of subject property and a set 3/4 inch and 24 inches long rebar with a 3 $\frac{3}{4}$ inch aluminum cap; thence south a distance of 65.0 feet to the southeast corner of subject property and a set 3/4 inch and 24 inches long rebar with a 3 $\frac{3}{4}$ inch aluminum cap, said southeast corner being located on said east-west centerline of said Section 10; thence south 89° 48' west, a distance of 431.8 feet to the POINT OF BEGINNING of subject property.

The area described contains 0.64 acres, more or less in Bonner County.

3. At 9 a.m. on February 2, 2009, the lands described as the S $\frac{1}{2}$ NE $\frac{1}{4}$, of sec. 10, T. 54 N., R. 1 W., Boise Meridian, and the lands described in Paragraph 2 above and aggregating 80.64 acres, shall be opened to such forms of disposition as may by law be made of National Forest System lands, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

Dated: December 12, 2008.

C. Stephen Allred,*Assistant Secretary—Land and Minerals Management.*

[FR Doc. E8-31229 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-11-P**DEPARTMENT OF THE INTERIOR****Bureau of Land Management****[CA-930; CACA 7670 and CACA 7672]****Public Land Order No. 7723; Partial Revocation of Lighthouse Withdrawals Created by Two Executive Orders and Transfer of Administrative Jurisdiction; California****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Public land order.

SUMMARY: This order partially revokes the withdrawals created by two Executive Orders insofar as they affect approximately 700 acres of public lands reserved for lighthouse purposes. This order also transfers administrative jurisdiction of the lands to the National Park Service to be managed as part of the Channel Islands National Park. The United States Coast Guard has determined the reservations are no longer needed.

DATES: January 2, 2009.**FOR FURTHER INFORMATION CONTACT:**

Duane Marti, BLM California State Office (CA-930), 2800 Cottage Way, Suite W-1834, Sacramento, California 95825-1886; 916-978-4675.

SUPPLEMENTARY INFORMATION: The public lands comprise Anacapa Island, which consists of three islets, and Cat Rock; all of which are located in the Pacific Ocean, approximately 14 miles west of the coast of California. The Act of Congress dated March 5, 1980 (16 U.S.C. 410ff and 410ff-1 (2000)), established the Channel Islands National Park and authorized the Secretary of the Interior to transfer administrative jurisdiction of Federal property located within the park boundary to the National Park Service. The lands have been and will continue to be closed to all forms of appropriation under the public land laws, including mining and mineral leasing.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

1. The withdrawals created by Executive Orders dated September 11,

1854 and January 26, 1867, which withdrew public lands from surface entry and mining and reserved them for lighthouse purposes, are hereby revoked insofar as they affect the following lands:

San Bernardino Meridian

Unsurveyed T. 2 S., Rgs. 24 and 25 W.

All of that part of the Anacapa Island Lighthouse Reservation, a group of three islets known as Anacapa Island, including the following described parcels of land:

Parcel 1 All of the land comprising the east islet of the group lying eastward of West Longitude 119° 23' 38" (North American Datum 1927) comprising 106.88 acres, more or less;

Parcel 2 All of the land comprising the middle islet lying between West Longitude 119° 23' 21" and 119° 23' 30" and south of Latitude 34° 00' 14" North comprising 7.68 acres, more or less;

Parcel 3 All of the land comprising the west islet, lying westward of West Longitude 119° 26' 10" comprising 46.72 acres, more or less; and

Parcel 4 The entire area of Cat Rock, which lies off the southern extremity of the west islet comprising 0.5 acre more or less; and all the remaining lands originally withdrawn for lighthouse purposes and incorporated into the Channel Islands National Monument by Presidential Proclamation No. 2281, containing 538.22 acres, more or less.

The areas described aggregate approximately 700 acres in Ventura County.

2. Subject to valid existing rights, the administrative jurisdiction of the public lands described above in Paragraph 1 is hereby transferred to the National Park Service, pursuant to Section 202 of the Act of Congress dated March 5, 1980, (16 U.S.C. 410ff-1 (2000)).

3. The public lands described above in paragraph 1 are located within the exterior boundary of the Channel Islands National Park, and shall be administered as part of that park in accordance with applicable Federal laws and regulations.

Dated: December 16, 2008.

C. Stephen Allred,*Assistant Secretary—Land and Minerals Management.*

[FR Doc. E8-31242 Filed 12-31-08; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management****[NM-120-1430-ET; NMMN 113684]****Public Land Order No. 7721; Withdrawal of National Forest System Land for Water Canyon Recreation Area Expansion; New Mexico****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Public land order.

SUMMARY: This order withdraws 65 acres of National Forest System land from location and entry under the United States mining laws for a period of 20 years on behalf of the Forest Service to protect the expansion to the Water Canyon Recreation Area. The land has been and will remain open to such forms of disposition as may by law be made of National Forest System land and to mineral leasing.

DATES: *Effective Date:* January 2, 2009.

ADDRESSES: Socorro Field Office Manager, Bureau of Land Management, 901 S. Highway 85, Socorro, New Mexico 87801, and to the U.S. Forest Service Supervisor, Cibola National Forest, 2113 Osuna Road, NE., Suite A., Albuquerque, New Mexico 87113.

FOR FURTHER INFORMATION CONTACT: Doug Williams, Cibola National Forest, at the above address or at (505) 346-3869.

SUPPLEMENTARY INFORMATION: The Forest Service will manage the land to protect the unique recreational and historical values and the investment of Federal funds at the Water Canyon Recreation Area. This is an expansion of the original recreation area which was withdrawn by Public Land Order No. 1155 (20 FR 3876 (1955)).

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land is hereby withdrawn from location and entry under the United States mining laws, (30 U.S.C. Ch.2 (2000)), to protect the unique recreational and historical values and the investment of Federal funds at the expansion of the Water Canyon Recreation Area:

New Mexico Principal Meridian*Cibola National Forest*

T. 3 S., R. 3 W.,

Sec. 27, S¹/₂N¹/₂NE¹/₄NE¹/₄, S¹/₂NE¹/₄NE¹/₄, SE¹/₄NE¹/₄NW¹/₄NE¹/₄,NE¹/₄SE¹/₄NW¹/₄NE¹/₄, W¹/₂NE¹/₄SE¹/₄NE¹/₄, W¹/₂SE¹/₄NE¹/₄, and N¹/₂NW¹/₄NE¹/₄SE¹/₄.

The area described contains 65 acres in Socorro County.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of National Forest System land under lease, license, or permit, or governing the disposal of the mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (2000), the Secretary determines that the withdrawal shall be extended.

Dated: December 12, 2008.

C. Stephen Allred,*Assistant Secretary—Land and Minerals Management.*

[FR Doc. E8-31244 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-11-P**DEPARTMENT OF THE INTERIOR****Bureau of land management****[NM-030-1920-ET; NMMN 117830]****Public Land Order No. 7724; Withdrawal of Public Land for Customs and Border Protection; New Mexico****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Public land order.

SUMMARY: This order withdraws 20 acres of public land from surface entry and mining for a period of 20 years and transfers administrative jurisdiction to the Department of Homeland Security, Customs and Border Protection for their Deming Station Forward Operating Base.

DATES: *Effective Date:* January 2, 2009.

ADDRESSES: Las Cruces District Manager, Bureau of Land Management, 1800 Marquess Street, Las Cruces, New Mexico 88005, and to the U.S. Department of Homeland Security, Customs and Border Protection, 441 Duncan Highway, Lordsburg, New Mexico 88045.

FOR FURTHER INFORMATION CONTACT: Lori Allen, Bureau of Land Management, at the above address or at (575) 525-4454.

SUPPLEMENTARY INFORMATION: This withdrawal and transfer of administrative jurisdiction will allow for improved effectiveness of operations

and protection of the Federal capital investment in the Deming Station Forward Operating Base.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

1. Subject to valid existing rights, the following described public land is hereby withdrawn from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (2000)), and administrative jurisdiction is transferred to the Department of Homeland Security, Customs and Border Protection for the Deming Station Forward Operating Base:

New Mexico Principal Meridian

T. 29 S., R. 12 W.,

Sec. 3, E¹/₂SW¹/₄NE¹/₄.

The area described contains 20 acres in Luna County.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of public land under lease, license, or permit or governing the disposal of their mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (2000), the Secretary determines that the withdrawal shall be extended.

Dated: December 17, 2008.

C. Stephen Allred,*Assistant Secretary—Land and Minerals Management.*

[FR Doc. E8-31243 Filed 12-31-08; 8:45 am]

BILLING CODE 4310-VC-P**DEPARTMENT OF THE INTERIOR****National Park Service****Notice of Inventory Completion: Bishop Museum, Honolulu, HI; Correction**

AGENCY: National Park Service, Interior.
ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession and control of the Bishop Museum, Honolulu, HI. The

human remains were removed from the Island of Kauai, HI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects a Notice of Inventory Completion published in the **Federal Register** on August 13, 2007, (FR Doc E7-15822, Page 45269), by amending the list of Native Hawaiian Organizations determined to be culturally affiliated with the human remains removed from sites on the Island of Kauai.

In the **Federal Register** of August 13, 2007, the notice is corrected by substituting the following for paragraphs 10 and 11:

Officials of the Bishop Museum have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of a minimum of six individuals of Native Hawaiian ancestry. Officials of the Bishop Museum also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native Hawaiian human remains and Hui Malama I Na Kupuna O Hawaii Nei and Kauai/Niihau Island Burial Council. Based upon information provided regarding geographical relationship and kinship traditions, Bishop Museum has determined the Kauai/Niihau Island Burial Council to be the most appropriate claimant.

Representatives of any other Indian tribe or Native Hawaiian organization that believes itself to be culturally affiliated with the human remains should contact Betty Lou Kam, Vice President, Cultural Resources, Bishop Museum, 1525 Bernice Street, Honolulu, HI 96817, telephone (808) 808-4144, before February 2, 2009. Repatriation of the human remains to the Kauai/Niihau Island Burial Council may proceed after that date if no additional claimants come forward.

The Bishop Museum is responsible for notifying Hui Malama I Na Kupuna O Hawaii Nei and Kauai/Niihau Island Burial Council that this notice has been published.

Dated: December 8, 2008

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8-30904 Filed 12-31-08; 8:45 am]

BILLING CODE 4312-50-S

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-505]

Use of the "First Sale Rule" for Customs Valuation of U.S. Imports

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

SUMMARY: Pursuant to section 15422(c)(1) of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110-234) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the Commission has instituted investigation No. 332-505, *Use of the "First Sale Rule" for Customs Valuation of U.S. Imports*, for the purpose of preparing the report required by section 15422(c)(1).

DATES:

April 30, 2009: Deadline for filing written submissions.

February 2010: Anticipated transmittal of Commission report to Congress.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

FOR FURTHER INFORMATION CONTACT: For information specific to this investigation, contact project leader Michael Ferrantino (202-205-3241 or michael.ferrantino@usitc.gov) or deputy project leader Nannette Christ (202-205-3263 or nannette.christ@usitc.gov). For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202-205-3091 or william.gearhart@usitc.gov). The media should contact Margaret O'Laughlin, Office of External Relations (202-205-1819 or margaret.olaughlin@usitc.gov). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet site (<http://www.usitc.gov>). 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.

Background: Section 15422(c)(1) of the Food, Conservation, and Energy Act of 2008 ("2008 Act"), enacted on May 22, 2008, requires the Commission to submit a report to the House Committee on Ways and Means and the Senate Committee on Finance that contains certain customs transaction valuation information compiled by the Commission from information furnished to the Commission by the Commissioner of U.S. Customs and Border Protection (CBP). Section 15422(c)(2) requires that the Commission include the following information in its report:

(1) The aggregate number of importers that declare the transaction value of the imported merchandise is determined on the basis of the method described in section 15422(a)(2) of the 2008 Act, including a description of the frequency of the use of such method;

(2) The tariff classification of such imported merchandise under the Harmonized Tariff Schedule of the United States (HTS) on an aggregate basis, including an analysis of the tariff classification of such imported merchandise on a sectoral basis;

(3) The aggregate transaction value of such imported merchandise, including an analysis of the transaction value of such imported merchandise on a sectoral basis; and

(4) The aggregate transaction value of all merchandise imported into the United States during the 1-year period specified in section 15422(a)(3).

To assist the Commission in preparing its report, section 15422(b) of the 2008 Act requires that the Commissioner of CBP provide monthly reports to the Commission, covering the period August 20, 2008-August 19, 2009, that include (1) the number of importers that declare the transaction value of the imported merchandise is determined on the basis of first or earlier sale, (2) the tariff classification of such imported merchandise under the HTS, and (3) the transaction value of such imported merchandise. The 2008 Act requires the Commission to submit its report 90 days after receipt of the final monthly report from CBP. The Commission expects to receive the final monthly report from CBP in November 2009 and therefore expects to transmit its report to the committees in February 2010.

The Commission has also instituted this investigation under section 332(g) of the Tariff Act of 1930 to facilitate docketing of submissions and public access to Commission records through the Commission's EDIS electronic records system.

Written Submissions: The Commission does not plan to hold a public hearing in the course of this investigation. Interested parties are, however, invited to submit written statements containing information and their views. All such statements should be addressed to the Secretary and should be received not later than 5:15 p.m., April 30, 2009. All statements must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8), which requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see *Handbook for Electronic Filing Procedures*, http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf); persons with questions regarding electronic filing should contact the Office of the Secretary at 202-205-2000.

Any submission that contains confidential business information must also conform with the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary for inspection by interested parties.

The Commission anticipates that the report it sends to the committees in this investigation will be made available to the public in its entirety. Consequently, the report that the Commission sends to the committees will not contain any confidential business information. Any confidential business information received by the Commission in this investigation and used in preparing its report will not be published in a manner that would reveal the operations of the firm supplying the information.

Issued: December 29, 2008.

By order of the Commission.
Marilyn R. Abbott,
Secretary to the Commission.
 [FR Doc. E8-31228 Filed 12-31-08; 8:45 am]
BILLING CODE 7020-02-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2008-0043]

Addenda to the Memorandum of Understanding: To Formalize the Working Relationship Between the Department of Energy and the Department of Labor

AGENCY: The Department of Labor; Occupational Safety and Health Administration (OSHA).

ACTION: Addenda to Memorandum of Understanding between the Department of Labor and the Department of Energy: (1) the construction of the Theory and Computing Sciences (TCS) building at the Argonne National Laboratory in Illinois; transfer of employee safety and health authority from the Department of Energy (DOE) to the Occupational Safety and Health Administration (OSHA); (2) the operations of six existing buildings and support facilities at the East Tennessee Technology Park in Oak Ridge, Tennessee; transfer of employee safety and health authority from DOE to the Tennessee Occupational Safety and Health Administration.

SUMMARY: This document is a notice of addenda to the August 28, 1992 interagency Memorandum of Understanding (MOU) between the U.S. Department of Labor and the U.S. Department of Energy. That MOU states that DOE has exclusive authority over the occupational safety and health of contractor employees at DOE Government-Owned and Contractor-Operated facilities (GOCOs). In addition, the MOU between the departments dated July 25, 2000, on safety and health enforcement at privatized facilities and operations provides that OSHA has regulatory authority over occupational safety and health at certain privatized facilities and operations on DOE land leased to private enterprises. This action is taken in accordance with the MOU of July 25, 2000, which establishes specific interagency procedures for the transfer of occupational safety and health coverage for such privatized facilities and operations from DOE to OSHA and state agencies acting under state plans approved by OSHA pursuant to section

18 of the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. 667. The MOUs may be found on the internet via the OSHA Web page <http://www.osha.gov> under the "D" for Department of Energy Transition Activities.

DATES: The effective date for the publication of this notice January 2, 2009.

FOR FURTHER INFORMATION: Contact Ms. MaryAnn Garrahan, Office of Technical Programs and Coordination Activities, Room N-3655, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 693-2110; fax (202-693-1644). Access electronic copies of this notice at OSHA's Web site, <http://www.osha.gov>, by selecting **Federal Register**, "Date of Publication," and then "2008."

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE) and the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor (DOL) entered into a Memorandum of Understanding (MOU) on August 10, 1992, delineating regulatory authority over the occupational safety and health of contractor employees at DOE government-owned or leased, contractor-operated (GOCO) facilities. In general, the memorandum of understanding recognizes that DOE exercises statutory authority under section 161(f) of the Atomic Energy Act of 1954, as amended, [42 U.S.C. 2201(f)], relating to the occupational safety and health of private-sector employees at these facilities.

Section 4(b)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 653(b)(1), exempts from OSHA authority working conditions with respect to which other federal agencies have exercised statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. The 1992 MOU acknowledges DOE's extensive regulation of contractor health and safety which requires contractor compliance with all OSHA standards as well as additional requirements prescribed by DOE, and concludes with an agreement by the agencies that the provisions of the Occupational Safety and Health Act will not apply to GOCO sites for which DOE has exercised its authority to regulate occupational safety and health under the Atomic Energy Act.

In light of DOE's policy emphasis on privatization activities, OSHA and DOE entered into a second Memorandum of Understanding on July 25, 2000; that establishes interagency procedures to address regulatory authority for

occupational safety and health at specified privatized facilities and operations on DOE sites. The 2000 Memorandum of Understanding specifically covers facilities and operations on lands that have been leased to private enterprises, which are not conducting activities for or on behalf of DOE, and where there is no likelihood that any employee exposure to radiation from DOE sources would be 25 millirems per year (mrem/yr) or more.

In a letter dated February 27, 2007, DOE requested that OSHA accept occupational safety and health regulatory authority at two locations pursuant to the MOU on Safety and Health Enforcement at Privatized Facilities and Operations, dated July 25, 2000. The request was for OSHA to accept regulatory oversight for the construction phase of the Theory and Computing Sciences (TCS) building at the Argonne National Laboratory in Illinois, as well as the transfer of oversight for six existing buildings and support facilities at the East Tennessee Technology Park (ETTP) in Oak Ridge, Tennessee.

OSHA's Regional Office in Chicago, IL, working with OSHA's Aurora Area Office, determined that OSHA should accept authority for the construction phase of the Theory and Computing Sciences (TCS) building at the Argonne National Laboratory in Illinois. The Aurora Area Office has been in contact with the DOE, as well as with the general contractor, regarding the construction phase of the project. These offices are satisfied with DOE assurances that (1) this facility is operationally independent of DOE activities during the construction phase, (2) there is no likelihood that any employee exposure to radiation will be 25 millirems per year (mrem /yr) or more, and (3) the transfer of authority to OSHA is free from regulatory gaps, and does not diminish the safety and health protection of the employees. OSHA, therefore, accepted health and safety regulatory authority for the construction phase of the TCS building. When construction of the TCS is complete, DOE will contact OSHA to inform it of the type of work to be performed at the completed TCS.

OSHA's Regional Office in Atlanta, GA, working with the OSHA Nashville Area Office, and the Tennessee Occupational Safety and Health Administration (TOSHA), determined that TOSHA is willing to accept authority for the six existing buildings and support facilities at the East Tennessee Technology Park in Oak Ridge, Tennessee that were transferred

by deed to the Community Reuse Organization of East Tennessee (CROET). TOSHA is satisfied with DOE assurances that (1) there is no likelihood that any employee at these facilities will be exposed to radiation levels that will be 25 millirems per year (mrem/yr) or more, and (2) transfer of authority to TOSHA is free from regulatory gaps, and does not diminish the safety and health protection of the employees. Therefore, TOSHA accepted and maintains health and safety regulatory authority over buildings K-1007, K-1225, K-1330, K-1400, K-1580, K-1007A, and K-1036. Accordingly, after reviewing pertinent information, OSHA and TOSHA, in a letter to DOE dated December 18, 2007, agreed to accept regulatory authority for occupational safety and health over these sites.

This **Federal Register** notice provides public notice and serves as an addendum to the 1992 OSHA/DOE MOU. This document was prepared under the direction of Thomas M. Stohler, Acting Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210. This action is taken pursuant to section 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g)) and Secretary of Labor's Order No. 5-2007 (72 FR 31159).

Signed at Washington, DC, December 15, 2008.

Thomas M. Stohler,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E8-31135 Filed 12-31-08; 8:45 am]

BILLING CODE 4510-26-P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 09-04]

Report on the Selection of Eligible Countries for Fiscal Year 2009

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, Public Law 108-199, Division D, (the "Act"), 22 U.S.C. 7708(d)(1).

The Act authorizes the provision of Millennium Challenge Account ("MCA") assistance under section 605 of the Act to countries that enter into compacts with the United States to support policies and programs that advance the progress of such countries in achieving lasting economic growth

and poverty reduction, and are in furtherance of the Act. The Act requires the Millennium Challenge Corporation ("MCC") to take steps to determine the countries that, based on their demonstrated commitment to just and democratic governance, economic freedom, and investing in their people, as well as the opportunity to reduce poverty and generate economic growth in the country, will be eligible to receive MCA assistance during the fiscal year. These steps include the submission of reports to appropriate congressional committees and the publication of notices in the **Federal Register** that identify, among other things:

1. The countries that are "candidate countries" for MCA assistance during FY09 based on their per-capita income levels and their eligibility to receive assistance under U.S. law, and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act; 22 U.S.C. 7708(a));

2. The criteria and methodology that the Board of Directors of MCC (the Board) will use to measure and evaluate the relative policy performance of the candidate countries consistent with the requirements of section 607 of the Act in order to select "MCA eligible countries" from among the "candidate countries" (section 608(b) of the Act, 22 U.S.C. 7708(b)); and

3. The list of countries determined by the Board to be "MCA eligible countries" for FY09, with justification for eligibility determination and selection for compact negotiation, including which of the MCA eligible countries the Board will seek to enter into MCA compacts (section 608(d) of the Act, 22 U.S.C. 7708(d)).

This is the third of the above-described reports by MCC for fiscal year 2009 (FY09). It identifies countries determined by the Board to be eligible under section 607 of the Act for FY09 (22 U.S.C. 7706) and countries with which the Board will seek to enter into compacts under section 609 of the Act, as well as the justification for such decisions.

Eligible Countries

The Board met on December 11, 2008 to select countries that will be eligible for MCA compact assistance under section 607 of the Act for FY09. The Board selected the following countries as eligible for such assistance for FY09: Colombia, Indonesia, Jordan, Malawi, Moldova, the Philippines, Senegal, and Zambia.

In accordance with the Act and with the "Report on the Criteria and Methodology for Determining the

Eligibility of Candidate Countries for Millennium Challenge Account Assistance in Fiscal Year 2009” submitted to the Congress on October 9, 2008, selection was based primarily on a country’s overall performance in relation to three broad policy categories: (1) “Ruling Justly”; (2) “Encouraging Economic Freedom”; and (3) “Investing in People.” The Board relied upon 17 transparent and independent indicators to assess to the maximum extent possible policy performance and demonstrated commitment in these three areas as a basis for determining which countries would be eligible for MCA compact assistance. In determining eligibility, the Board considered if a country performed above the median in relation to its peers on at least half of the indicators in the Ruling Justly and Economic Freedom policy categories, above the median on at least three of five indicators in the Investing in People policy category, and above the median on the “Control of Corruption” indicator. The Board also took into account whether the country performed substantially below the median on any indicator and if so, whether it is taking appropriate action to address the shortcomings. Scorecards reflecting each country’s performance on the indicators are available on MCC’s Web site at <http://www.mcc.gov>.

The Board also considered whether any adjustments should be made for data gaps, lags, trends, or recent events since the indicators were published, as well as strengths or weaknesses in particular indicators. Where appropriate, the Board took into account additional quantitative and qualitative information, such as evidence of a country’s commitment to fighting corruption and promoting democratic governance, and its effective protection of human rights. In addition, the Board considered the opportunity to reduce poverty and promote economic growth and poverty reduction in a country, in light of the overall context of the information available, as well as the availability of appropriated funds.

Three countries were selected as eligible for the first time in FY09. Indonesia and Zambia, both low income candidates, were selected under section 606(a) of the Act (22 U.S.C. 7705(a)). Colombia, a lower middle income candidate, was selected under section 606(b) (22 U.S.C. 7705(b)) of the Act. All three of these countries: (1) Performed above the median in relation to their peers on at least half of the indicators in each of the three policy categories; (2) performed above the median on corruption; and (3) in cases where they performed substantially below the

median on an indicator, demonstrated that actions to address the problem are being taken or had data that did not accurately reflect their policy performance.

Indonesia meets MCC’s indicator criteria for the first time in FY09, after having made steady progress improving its Control of Corruption score over the past several years. The Government of Indonesia has demonstrated a strong commitment to fighting corruption: anti-corruption institutions have been strengthened and high-level anti-corruption investigations and prosecutions have become increasingly common. In addition to anti-corruption reforms, the Government has initiated a series of reforms to improve the investment climate. Indonesia is in its second year of a successful Threshold program that has focused on reducing corruption and improving immunization rates.

Zambia meets MCC’s indicator criteria for the first time this year, performing above the median on 16 of 17 indicators. Anti-corruption efforts are a high priority for the Government of Zambia, and performance on the Control of Corruption indicator has improved in recent years. Zambia is also nearing the end of a successful anti-corruption Threshold Program. In recent years, Zambia has moved to a relatively open environment for investment and has demonstrated prudent macroeconomic management.

Colombia meets the indicator criteria for the second year in row. The Government of Colombia has pursued a significant reform agenda, including major tax, civil service, and justice sector reforms. Colombia has also been cited as a top reformer by the World Bank’s *Doing Business* report for two years in a row. In addition, President Uribe’s strategy to expand the professional armed forces and promote a strong state presence throughout the country has yielded significant results in terms of improving security. While the U.S. Government provides a substantial amount of assistance to Colombia through other accounts, the majority has gone toward counternarcotics aid.

Five countries selected as eligible for MCA assistance in FY09 were previously selected as eligible in at least one prior fiscal year; however, because they have not yet signed a compact agreement, they needed to be reselected as eligible for FY09 funds. Four of these countries were in the low income category: Malawi, Moldova, the Philippines, and Senegal. One country, Jordan, was in the lower middle income category.

The Board reselected these countries based on their continued performance since their prior selection. The Board determined that no material change has occurred in the performance of these countries on the indicator criteria since the FY08 selection that would justify not including them in the FY09 eligible country list. Only one of the countries—the Philippines—did not meet the indicator criteria, performing just below the median on the Control of Corruption indicator; however, MCC does not believe that the Philippines has demonstrated a pattern of action inconsistent with the selection criteria (i.e., a serious policy reversal) since it was last selected as eligible. The Board also stressed that the Philippines must meet the selection criteria, particularly the Control of Corruption indicator, before it would approve a compact.

Country partners which are implementing compacts must show a commitment to maintain and improve their policy performance. Once we sign a compact with these countries, they will not need to be reselected annually. MCC’s Board closely evaluates a country’s policy performance throughout the life of the compact. While MCC’s indicators work well as a transparent way of identifying those countries that are most committed to sound development policies and for discerning trends over the medium-term, they are not as well-suited for tracking incremental progress from year-to-year. Countries may be *generally* maintaining performance but not meet the criteria in a given year due to factors such as:

- Graduation from the low income country category to the lower middle income country category,
- Data improvements and revisions,
- Last year’s introduction of two new indicators and the requirement that countries pass three of the five indicators in the Investing in People category,
- Increases in peer-group medians,
- Slight declines in performance.

Once MCC has made a commitment to a country through a signed compact, MCC continues to work with that country—even if it doesn’t meet the indicator criteria each year—as long as it has not demonstrated a pattern of actions inconsistent with the eligibility criteria. If it is determined that a country has demonstrated a significant policy reversal, the Board can hold it accountable by applying the Suspension and Termination Policy.

For those countries that have not demonstrated a significant policy reversal but do not meet the indicator criteria, MCC will invite these countries

to participate or continue their participation in MCC's policy improvement process. Countries participating in the policy improvement process are asked to develop and implement a forward-looking action plan that outlines the steps they plan to take to improve performance on certain policy criteria. They then periodically report on progress made on the plan.

Finally, a number of countries that performed well on the quantitative elements of the selection criteria (i.e., on the policy indicators) were not chosen as eligible countries for FY09. As discussed above, the Board considered a variety of factors in addition to the country's performance on the policy indicators in determining whether they were appropriate candidates for assistance (e.g., the country's commitment to fighting corruption and promoting democratic governance; the availability of appropriated funds; and the countries in which MCC would likely have the best opportunity to reduce poverty and generate economic growth).

Selection for Compact Negotiation

The Board also authorized MCC to invite Indonesia, Zambia, and Colombia to submit a proposal for a compact, as described in section 609 of the Act (22 U.S.C. 7708) (previously eligible countries that were reselected will not be asked to submit another proposal for FY09 assistance). MCC has posted guidance on the MCC Web site (<http://www.mcc.gov>) regarding the development and submission of MCA program proposals. Submission of a proposal is not a guarantee that MCC will finalize a compact with an eligible country. Any MCA assistance provided under section 605 of the Act will be contingent on the successful negotiation of a mutually agreeable compact between the eligible country and MCC, approval of the compact by the Board, and availability of funds.

Dated: December 22, 2008.

John C. Mantini,

Acting General Counsel, Millennium Challenge Corporation.

[FR Doc. E8-30965 Filed 12-31-08; 8:45 am]

BILLING CODE 9211-03-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-255]

Entergy Nuclear Operations, Inc.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-20 issued to Entergy Nuclear Operations, Inc. (ENO, the licensee), for operation of the Palisades Nuclear Plant located in Covert, Michigan.

The proposed amendment would revise Appendix A, Technical Specifications (TS), as they apply to the spent fuel pool (SFP) storage requirements in TS section 3.7.16 and the criticality requirements for the Region I SFP and north tilt pit fuel storage racks, in TS section 4.3.1.1.

The proposed change, in accordance with Title 10 of *Code of Federal Regulations* (10 CFR) 50.68, Criticality accident requirements, would establish the effective neutron multiplication factor (Keff) limits for Region I storage racks based on analyses to maintain Keff less than 1.0 when flooded with unborated water, and less than, or equal to (\leq) 0.95 when flooded with water having a minimum boron concentration of 850 parts per million (ppm) during normal operations. The proposed change was evaluated for both normal operation and accident conditions. This proposed change provides an analysis that does not credit boron in the Carborundum[®] poison plates and incorporates a conservative swelling model of the plates in the Region I storage racks.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3)

involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

There is no significant increase in the probability of an accidental misloading of fuel assemblies into the spent fuel pool racks when considering the presence of soluble boron in the pool water for criticality control. Fuel assembly placement would continue to be controlled by approved fuel handling procedures and would be in accordance with the TS fuel storage rack configuration limitations.

There is no significant increase in the consequences of the accidental misloading of fuel assemblies into the spent fuel pool racks because the criticality analyses demonstrate that the pool would remain subcritical with margin following an accidental misloading if the pool contains an adequate boron concentration. The TS 3.7.15 limitation on minimum spent fuel pool boron concentration and plant procedures ensure that an adequate boron concentration will be maintained.

There is no significant increase in the probability of a fuel assembly drop accident in the spent fuel pool when considering the presence of soluble boron in the spent fuel pool water for criticality control. The handling of fuel assemblies in the spent fuel is performed in borated water. The criticality analysis has showed the reactivity increase with a fuel assembly drop accident in both a vertical and horizontal orientation is bounded by the misloading accident. Therefore, the consequences of a fuel assembly drop accident in the spent fuel pool would not increase significantly due to the proposed change.

The spent fuel pool TS boron concentration requirement in TS 3.7.15 requires a minimum of 1720 ppm which bounds the analysis. Soluble boron has been maintained in the spent fuel pool water as required by TS and controlled by procedures. The present criticality safety analyses for Region II of the spent fuel pool credits the same soluble boron concentration of 850 ppm to maintain a Keff \leq 0.95 under normal conditions and 1350 ppm to maintain a Keff \leq 0.95 under accident scenarios as do the analyses for the proposed change for Region I. Crediting soluble boron in the Region I spent fuel pool criticality analysis would have no effect on normal pool operation and maintenance. Thus, there is no change to the probability or the consequences of the boron dilution event in the spent fuel pool.

Since soluble boron is maintained in the spent fuel pool water, implementation of the proposed changes would have no effect on the normal pool operation and maintenance. Also, since soluble boron is present in the spent fuel pool a dilution event has always been a possibility. The loss of substantial amounts of soluble boron from the spent fuel

pool was evaluated as part of the analyses in support of this proposed amendment. The analyses use the same soluble boron concentrations as were used in previous analyses for Region II spent fuel storage racks. In the unlikely event that soluble boron in the spent fuel pool is completely diluted, the fuel in Region I of the spent fuel pool would remain subcritical by a design margin of at least 0.02 delta Keff, so the Keff of the fuel in Region I will remain below 1.0. Therefore, the limitations on boron concentration have not changed and would not result in a significant increase in the probability or consequences of a previously evaluated accident.

There is no increase in the probability or consequences of the loss of normal cooling to the spent fuel pool water, when considering the presence of soluble boron in the pool water for subcriticality control, since a high concentration of soluble boron is always maintained in the spent fuel pool.

The criticality analyses documented in AREVA NP report ANP-2779NP-001, "Palisades SFP Region I Criticality Evaluation," show, at a 0.95% [percent] probability and a 95% confidence level (95/95) that Keff is less than the regulatory limit in 10 CFR 50.68 of 0.95 under borated conditions, or a limit of 1.0 with unborated water. Therefore, the consequences of accidents previously evaluated are not increased.

Therefore, it is concluded that the proposed change does not significantly increase the probability or consequences of any 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.

Spent fuel handling accidents have been analyzed in Sections 14.11, "Postulated Cask Drop Accidents," and 14.19, "Fuel Handling Incident," of the Updated Final Safety Analysis Report. Criticality accidents in the spent fuel pool have been analyzed in previous criticality evaluations, which are the bases for the present TS.

The existing TS allow storage of fuel assemblies with a maximum planar average U-235 enrichment of 4.95 weight percent in the Region I fuel storage rack. The proposed specifications would restrict fuel enrichment to lower values in different areas of the Region I storage racks. The possibility of placing a fuel assembly with greater enrichment than allowed currently exists but is controlled by fuel manufacturer's procedures and plant handling procedures. Manufacturer's and plant procedu[r]al controls would remain in place. Lowering the allowed enrichments does not create a new or different kind of accident.

ENO considered the effects of a mispositioned fuel assembly. The proposed loading restrictions include locations that are prohibited from containing any fuel. Administrative controls are in place to restrict fuel moves to those locations. These include procedures to develop the plans for fuel movement and operate the fuel handling equipment. These procedures include appropriate reviews and verifications to

ensure design requirements are maintained. ENO is also proposing to add new limiting conditions for operation and surveillance requirements in TS 3.7.16 to provide additional assurance that the requirements are met.

Furthermore, the existing TS contain limitations on the spent fuel pool boron concentration that conservatively bound the required boron concentration of the new criticality analyses. Currently, TS 3.7.15 requires a minimum boron concentration of 1720 ppm. Since soluble boron is maintained in the spent fuel pool water, implementation of the proposed changes would have no effect on the normal pool operation and maintenance. Since soluble boron is present in the spent fuel pool, a dilution event has always been a possibility. The loss of substantial amounts of soluble boron from the spent fuel pool was evaluated as part of the analysis in support of Amendment 207. That analysis also demonstrated that due to the large volume of unborated water that would need to be added and displaced, and the long duration of the event, the condition would be detected and corrected promptly. The analyses that support the current request use the same soluble boron concentrations as were used in previous analyses for Region II spent fuel storage racks. In the unlikely event that soluble boron in the spent fuel pool is completely diluted, the fuel in Region I of the spent fuel pool would remain subcritical by a design margin of at least 0.02 delta Keff, so the Keff of the fuel in Region I would remain below 1.0.

The combination of controls to prevent a mispositioned fuel assembly, ability to readily identify and correct a dilution event, and relatively high concentration of soluble boron supports a conclusion that a new or different kind of accident is not created.

Under the proposed amendment, no changes are made to the fuel storage racks themselves, to any other systems, or to any plant structures. Therefore, the change will not result in any other change in the plant configuration or equipment design.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Detailed analysis with approved and benchmarked methods has shown with a 95% probability at a 95% confidence level, that the Keff, of the Region I fuel storage racks in the spent fuel pool, including biases, tolerances and uncertainties is less than 1.0 with unborated water, and less than or equal to 0.95 with 850 ppm of soluble boron credited. In addition, the effects of abnormal and accident conditions have been evaluated to demonstrate that under credible conditions the Keff will not exceed 0.95 with 1350 ppm soluble boron credited. The current TS requirement for minimum spent fuel pool boron concentration is 1720 ppm, which provides assurance that the spent fuel pool would remain subcritical.

The current analysis basis for the Region II fuel storage racks is a maximum Keff of less than 1.0 when flooded with unborated water,

and less than or equal to 0.95 when flooded with water having a boron concentration of 850 ppm. In addition, the Keff in accident or abnormal operating conditions is less than 0.95 with 1350 ppm of soluble boron. These values are not affected by the proposed change.

Therefore, it is concluded that the proposed change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 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, TWB-05-B01M, 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. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the 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(s) 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 O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. 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/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed by the above date, 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 identify 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 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 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 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, 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 electronic filing Help Desk, which is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday. The electronic filing Help Desk can be contacted by telephone at 1-866-672-7640 or by e-mail at MSHD.Resource@nrc.gov.

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, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

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 submissions.

For further details with respect to this license amendment application, see the application for amendment dated November 25, 2008, which is available for public inspection at the Commission's PDR, located at One White Flint North, File Public Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

Dated at Rockville, Maryland, this 19th day of December.

For the Nuclear Regulatory Commission.
Mahesh Chawla,
*Project Manager, Plant Licensing Branch
 3-1, Division of Operating Reactor Licensing,
 Office of Nuclear Reactor Regulation.*
 [FR Doc. E8-31207 Filed 12-31-08; 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 December 29, 2008; January 5, 12, 19, 26, February 2, 2009.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of December 29, 2008

There are no meetings scheduled for the week of December 29, 2008.

Week of January 5, 2009—Tentative

There are no meetings scheduled for the week of January 5, 2009.

Week of January 12, 2009—Tentative

There are no meetings scheduled for the week of January 12, 2009.

Week of January 19, 2009—Tentative

There are no meetings scheduled for the week of January 19, 2009.

Week of January 26, 2009—Tentative

There are no meetings scheduled for the week of January 26, 2009.

Week of February 2, 2009—Tentative

There are no meetings scheduled for the week of February 2, 2009.

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* 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: Rochelle Baval, (301) 415-1651.

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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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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301-492-2279, TDD: 301-415-2100, or by e-mail at rohn.brown@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

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: December 29, 2008.

Rochelle C. Baval,

Office of the Secretary.

[FR Doc. E8-31266 Filed 12-30-08; 4:15 pm]

BILLING CODE 7590-01-P

**NUCLEAR REGULATORY
COMMISSION****[Docket No. 50–289; License No. DPR–50]****In the Matter of AmerGen Energy
Company, LLC; Exelon Generation
Company, LLC (Three Mile Island
Nuclear Station, Unit 1); Order
Approving Transfer of License and
Conforming Amendment****I**

AmerGen Energy Company, LLC (AmerGen or licensee) is the holder of Facility Operating License No. DPR–50, which authorizes the possession, use, and operation of the Three Mile Island Nuclear Station, Unit 1 (TMI–1). AmerGen is a wholly owned subsidiary of Exelon Generation Company, LLC (EGC). The facility is located at the licensee's site in Dauphin County Pennsylvania.

II

By letter dated June 20, 2008, as supplemented on July 17, 2008 (together, the application), AmerGen and EGC submitted an application requesting approval of the transfer of the operating license for TMI–1 to the extent held by AmerGen, to EGC. There will be no physical changes to the facility, nor changes in officers, personnel, or day-to-day operations as a result of the transfer. There will be no change in the ownership of EGC, which is a wholly owned subsidiary of Exelon Ventures Company, LLC, which, in turn, is a wholly owned subsidiary of Exelon Corporation. The transfer to EGC will eliminate AmerGen as owner and operator of TMI–1. After the transfer, EGC will be the sole licensed owner and operator of TMI–1.

The applicants also requested approval of a conforming license amendment that would replace references to AmerGen in the license with references to EGC to reflect the transfer of ownership and operating authority, specifically, to possess, use and operate TMI–1 and to receive, possess, or use related licensed materials under the applicable conditions and authorizations included in the TMI–1 license.

Approval of the transfer of the license and the conforming license amendment is requested by the applicants pursuant to Sections 50.80 and 50.90 of Title 10 of the *Code of Federal Regulations* (10 CFR). Notice of the request for approval and opportunity for a hearing was published in the **Federal Register** on August 26, 2008 (73 FR 50370). No hearing requests or petitions to intervene were received. The Nuclear

Regulatory Commission (NRC, the Commission) received comments from a member of the public in Florham Park, New Jersey, in an e-mail dated August 27, 2008. The comments did not provide any information additional to that in the application, nor did they provide any information contradictory to that provided in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. Upon review of the information in the application and other information before the Commission, and relying upon the representations and agreements contained in the application, the NRC staff has determined that EGC is qualified to acquire and hold the ownership interest and operating authority previously held by AmerGen, and that the transfer of the license to EGC described in the application is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the conditions set forth below. The NRC staff has further found that the application for the proposed license amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendment can be conducted without endangering the health and safety of the public and that such activities will be conducted in compliance with the Commission's regulations; the issuance of the proposed license amendment will not be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed amendments will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

The findings set forth above are supported by the NRC staff's safety evaluation dated the same day as this Order.

III

Accordingly, pursuant to Sections 161b, 161i, and 184 of the Act, 42 U.S.C. Sections 2201(b), 2201(j), and 2234; and 10 CFR 50.80 and 10 CFR 72.50, *it is hereby ordered* that the transfer of the license from AmerGen to EGC, as

described herein, is approved, subject to the following conditions:

(1) Before completion of the transfer of TMI–1, EGC shall provide the Director of the Office of Nuclear Reactor Regulation satisfactory documentary evidence that EGC has obtained the appropriate amount of insurance required of licensees under 10 CFR Part 140 of the Commission's regulations.

(2) At the time of the closing of the transfer of TMI–1 and the respective license from AmerGen Energy Company, LLC (AmerGen) to Exelon Generation Company, AmerGen shall transfer to Exelon Generation Company ownership and control of AmerGen TMI NQF, LLC; and AmerGen Consolidation, LLC shall be merged into Exelon Generation Consolidation, LLC. Also at the time of the closing, decommissioning funding assurance provided by Exelon Generation Company, using an additional method allowed under 10 CFR 50.75 if necessary, must be equal to or greater than the minimum amount calculated on that date pursuant to, and required by 10 CFR 50.75 for TMI–1.

Furthermore, funds dedicated for TMI–1 prior to closing shall remain dedicated to TMI–1 following the closing. The name of AmerGen TMI NQF, LLC shall be changed to Exelon Generation TMI NQF, LLC at the time of the closing.

It is further ordered that, consistent with 10 CFR 2.1315(b), the license amendment that makes changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the license to reflect the subject direct license transfer is approved. The amendment shall be issued and made effective at the time the proposed direct license transfer is completed.

It is further ordered that AmerGen and EGC shall inform the Director of the Office of Nuclear Reactor Regulation, in writing, of the date of closing of the transfer of AmerGen's ownership and operating interests in TMI–1 at least 1 business day before the closing. Should the transfer of the license not be completed within 1 year of this Order's date of issuance, this Order shall become null and void, provided, however, that upon written application and for good cause shown, such date may be extended by order.

This Order is effective upon issuance.

For further details with respect to this Order, see the initial application dated June 20, 2008, and the safety evaluation with the same date as this Order, which are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Room O–1 F21 (First Floor), Rockville, Maryland, and

accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by e-mail at pdr.resource@nrc.gov.

Dated at Rockville, Maryland, this 23rd day of December 2008.

For the Nuclear Regulatory Commission.

Eric J. Leeds,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. E8-31209 Filed 12-31-08; 8:45 am]

BILLING CODE 7590-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-461; License No. NPF-62]

In the Matter of AmerGen Energy Company, LLC; Exelon Generation Company, LLC (Clinton Power Station, Unit No. 1); Order Approving Transfer of License and Conforming Amendment

I

AmerGen Energy Company, LLC (AmerGen or licensee) is the holder of Facility Operating License No. NPF-62, which authorizes the possession, use, and operation of Clinton Power Station, Unit No. 1 (Clinton or CPS). AmerGen is a wholly owned subsidiary of Exelon Generation Company, LLC (EGC). The facility is located at the licensee's site in DeWitt County, Illinois.

II

By letter dated June 20, 2008, as supplemented on July 17, 2008 (together, the application), AmerGen and EGC submitted an application requesting approval of the transfer of the operating license for CPS to the extent held by AmerGen, to EGC. There will be no physical changes to the facility, nor changes in officers, personnel, or day-to-day operations as a result of the transfer. There will be no change in the ownership of EGC, which is a wholly owned subsidiary of Exelon Ventures Company, LLC, which, in turn, is a wholly owned subsidiary of Exelon Corporation. The transfer to EGC will eliminate AmerGen as owner and operator of CPS. After the transfer, EGC will be the sole licensed owner and operator of CPS.

The applicants also requested approval of a conforming license amendment that would replace references to AmerGen in the license with references to EGC to reflect the transfer of ownership and operating authority, specifically, to possess, use and operate CPS and to receive, possess, or use related licensed materials under the applicable conditions and authorizations included in the CPS license.

Approval of the transfer of the license and the conforming license amendment is requested by the applicants pursuant to Sections 50.80 and 50.90 of Title 10 of the Code of Federal Regulations (10 CFR). Notice of the request for approval and opportunity for a hearing was published in the **Federal Register** on August 26, 2008 (73 FR 50368). No hearing requests or petitions to intervene were received. The Nuclear Regulatory Commission (NRC, the Commission) received comments from a member of the public in Florham Park, New Jersey, in an e-mail dated August 27, 2008. The comments did not provide any information additional to that in the application, nor did they provide any information contradictory to that provided in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. Upon review of the information in the application and other information before the Commission, and relying upon the representations and agreements contained in the application, the NRC staff has determined that EGC is qualified to acquire and hold the ownership interest and operating authority previously held by AmerGen, and that the transfer of the license to EGC described in the application is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the condition set forth below. The NRC staff has further found that the application for the proposed license amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendment can be conducted without endangering the health and safety of the public and that such activities will be

conducted in compliance with the Commission's regulations; the issuance of the proposed license amendment will not be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed amendments will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

The findings set forth above are supported by the NRC staff's safety evaluation dated the same day as this Order.

III

Accordingly, pursuant to Sections 161b, 161i, and 184 of the Act, 42 U.S.C. Sections 2201(b), 2201(i), and 2234; and 10 CFR 50.80 and 10 CFR 72.50, *it is hereby ordered* that the transfer of the license from AmerGen to EGC, as described herein, is approved, subject to the following conditions:

(1) Before completion of the transfer of CPS, EGC shall provide the Director of the Office of Nuclear Reactor Regulation satisfactory documentary evidence that EGC has obtained the appropriate amount of insurance required of licensees under 10 CFR Part 140 of the Commission's regulations.

(2) At the time of the closing of the transfer of CPS and the respective license from AmerGen Energy Company, LLC (AmerGen) to Exelon Generation Company, AmerGen shall transfer to Exelon Generation Company ownership and control of AmerGen Clinton NQF, LLC; and AmerGen Consolidation, LLC shall be merged into Exelon Generation Consolidation, LLC. Also at the time of the closing, decommissioning funding assurance provided by Exelon Generation Company, using an additional method allowed under 10 CFR 50.75 if necessary, must be equal to or greater than the minimum amount calculated on that date pursuant to, and required by 10 CFR 50.75 for CPS. Furthermore, funds dedicated for CPS prior to closing shall remain dedicated to CPS following the closing. The name of AmerGen Clinton NQF, LLC shall be changed to Exelon Generation Clinton NQF, LLC at the time of the closing.

It is further ordered that, consistent with 10 CFR 2.1315(b), the license amendment that makes changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the license to reflect the subject direct license transfer is approved. The amendment shall be issued and made effective at the time the proposed direct license transfer is completed.

It is further ordered that AmerGen and EGC shall inform the Director of the Office of Nuclear Reactor Regulation, in writing, of the date of closing of the transfer of AmerGen's ownership and operating interests in CPS at least 1 business day before the closing. Should the transfer of the license not be completed within 1 year of this Order's date of issuance, this Order shall become null and void, provided, however, that upon written application and for good cause shown, such date may be extended by order.

This Order is effective upon issuance.

For further details with respect to this Order, see the initial application dated June 20, 2008, and the safety evaluation with the same date as this Order, which are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Room O-1 F21 (First Floor), Rockville, Maryland, and accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by e-mail at pdr@nrc.gov.

Dated at Rockville, Maryland, this 23rd day of December 2008.

For the Nuclear Regulatory Commission.

Eric J. Leeds,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. E8-31211 Filed 12-31-08; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-219 and 72-15; License No. DPR-16]

In the Matter of: Amergen Energy Company, LLC Exelon Generation Company, LLC (Oyster Creek Nuclear Generating Station); Order Approving Transfer of License and Conforming Amendment

I

AmerGen Energy Company, LLC (AmerGen or licensee) is the holder of Facility Operating License No. DPR-16, which authorizes the possession, use, and operation of the Oyster Creek Nuclear Generating Station (Oyster Creek, or the facility). AmerGen is also authorized to store spent fuel at the

Oyster Creek Independent Spent Fuel Storage Installation pursuant to the general license provision in section 72.210 of Title 10 of the *Code of Federal Regulations* (10 CFR). AmerGen is a wholly owned subsidiary of Exelon Generation Company, LLC (EGC). The facility is located at the licensee's site in Ocean County, New Jersey.

II

By letter dated June 20, 2008, as supplemented on July 17, 2008 (together, the application), AmerGen and EGC submitted an application requesting approval of the transfer of the operating license for Oyster Creek to the extent held by AmerGen, to EGC. There will be no physical changes to the facility, nor changes in officers, personnel, or day-to-day operations as a result of the transfer. There will be no changes in the ownership of EGC, which is a wholly owned subsidiary of Exelon Ventures Company, LLC, which, in turn is a wholly owned subsidiary of Exelon Corporation. The transfer to EGC will eliminate AmerGen as owner and operator of TMI-1. After the transfer, EGC will be the sole licensed owner and operator of Oyster Creek.

The applicants also requested approval of a conforming license amendment that would replace references to AmerGen in the license with references to EGC to reflect the transfer of ownership and operating authority, specifically, to possess, use and operate Oyster Creek and to receive, possess, or use related licensed materials under the applicable conditions and authorizations included in the Oyster Creek license.

Approval of the transfer of the license and the conforming license amendment is requested by the applicants pursuant to sections 50.80 and 50.90 of 10 CFR. Notice of the request for approval and opportunity for a hearing was published in the **Federal Register** on August 26, 2008 (73 FR 50371). No hearing requests or petitions to intervene were received. The Nuclear Regulatory Commission (NRC, the Commission) received comments from a member of the public in Florham Park, New Jersey, in an e-mail dated August 27, 2008. The comments did not provide any information additional to that in the application, nor did they provide any information contradictory to that provided in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. Upon review of the information in the application

and other information before the Commission, and relying upon the representations and agreements contained in the application, the NRC staff has determined that EGC is qualified to acquire and hold the ownership interest and operating authority previously held by AmerGen, and that the transfer of the license to EGC described in the application is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the conditions set forth below. The NRC staff has further found that the application for the proposed license amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendment can be conducted without endangering the health and safety of the public and that such activities will be conducted in compliance with the Commission's regulations; the issuance of the proposed license amendment will not be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed amendments will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

The findings set forth above are supported by the NRC staff's safety evaluation dated the same day as this Order.

III

Accordingly, pursuant to sections 161b, 161i, and 184 of the Act, 42 U.S.C. sections 2201(b), 2201(i), and 2234; and 10 CFR 50.80 and 10 CFR 72.50, it is hereby ordered that the transfer of the license from AmerGen to EGC, as described herein, is approved, subject to the following conditions:

(1) Before completion of the transfer of Oyster Creek, EGC shall provide the Director of the Office of Nuclear Reactor Regulation satisfactory documentary evidence that EGC has obtained the appropriate amount of insurance required of licensees under 10 CFR part 140 of the Commission's regulations.

(2) At the time of the closing of the transfer of Oyster Creek and the respective license from AmerGen Energy Company, LLC (AmerGen) to Exelon Generation Company, AmerGen shall transfer to Exelon Generation

Company ownership and control of AmerGen Oyster Creek NQF, LLC; and AmerGen Consolidation, LLC shall be merged into Exelon Generation Consolidation, LLC. Also at the time of the closing, decommissioning funding assurance provided by Exelon Generation Company, using an additional method allowed under 10 CFR 50.75 if necessary, must be equal to or greater than the minimum amount calculated on that date pursuant to, and required by 10 CFR 50.75 for Oyster Creek. Furthermore, funds dedicated for Oyster Creek prior to closing shall remain dedicated to Oyster Creek following the closing. The name of AmerGen Oyster Creek NQF, LLC shall be changed to Exelon Generation Oyster Creek NQF, LLC at the time of the closing.

It is further ordered that, consistent with 10 CFR 2.1315(b), the license amendment that makes changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the license to reflect the subject direct license transfer is approved. The amendment shall be issued and made effective at the time the proposed direct license transfer is completed.

It is further ordered that AmerGen and EGC shall inform the Director of the Office of Nuclear Reactor Regulation, in writing, of the date of closing of the transfer of AmerGen's ownership and operating interests in Oyster Creek at least 1 business day before the closing. Should the transfer of the license not be completed within 1 year of this Order's date of issuance, this Order shall become null and void, provided, however, that upon written application and for good cause shown, such date may be extended by order.

This Order is effective upon issuance.

For further details with respect to this Order, see the initial application dated June 20, 2008, and the safety evaluation with the same date as this Order, which

are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Room O-1 F21 (First Floor), Rockville, Maryland, and accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by e-mail at pdr.resource@nrc.gov.

Dated at Rockville, Maryland, this 23rd day of December 2008.

For the Nuclear Regulatory Commission.

Eric J. Leeds,
Director, Office of Nuclear Reactor Regulation.

[FR Doc. E8-31206 Filed 12-31-08; 8:45 am]

BILLING CODE 7590-01-P

OFFICE OF MANAGEMENT AND BUDGET

Discount Rates for Cost-Effectiveness Analysis of Federal Programs

AGENCY: Office of Management and Budget.

ACTION: Revisions to Appendix C of OMB Circular A-94.

SUMMARY: The Office of Management and Budget revised Circular A-94 in 1992. The revised Circular specified certain discount rates to be updated annually when the interest rate and inflation assumptions used to prepare the Budget of the United States Government were changed. These discount rates are found in Appendix C of the revised Circular. The updated discount rates are shown below. The

discount rates in Appendix C are to be used for cost-effectiveness analysis, including lease-purchase analysis, as specified in the revised Circular. They do not apply to regulatory analysis.

DATES: The revised discount rates are effective immediately and will be in effect through December 2009.

FOR FURTHER INFORMATION CONTACT: Robert B. Anderson, Office of Economic Policy, Office of Management and Budget, (202) 395-3381.

John H. Kitchen,
Associate Director for Economic Policy, Office of Management and Budget.

OMB Circular No. A-94.

Appendix C

(Revised December 2008)

Discount Rates for Cost-Effectiveness, Lease Purchase, and Related Analyses

Effective Dates. This appendix is updated annually. This version of the appendix is valid for calendar year 2009. A copy of the updated appendix can be obtained in electronic form through the OMB home page at http://www.whitehouse.gov/omb/circulars/a094/a94_appx-c.html, the text of the main body of the Circular is found at <http://www.whitehouse.gov/omb/circulars/a094/a094.html>, and a table of past years' rates is located at <http://www.whitehouse.gov/omb/circulars/a094/DISCHIST-2009.pdf>. Updates of the appendix are also available upon request from OMB's Office of Economic Policy (202-395-3381).

Nominal Discount Rates. A forecast of nominal or market interest rates for 2009 based on the economic assumptions for the Fiscal Year 2010 December Budget Baseline are presented below. These nominal rates are to be used for discounting nominal flows, which are often encountered in lease-purchase analysis.

NOMINAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[In percent]

3-year	5-year	7-year	10-year	20-year	30-year
2.7	3.3	3.7	4.2	4.7	4.5

Real Discount Rates. A forecast of real interest rates from which the inflation premium has been removed and based

on the economic assumptions from the 2010 December Budget Baseline is presented below. These real rates are to

be used for discounting constant-dollar flows, as is often required in cost-effectiveness analysis.

REAL INTEREST RATES ON TREASURY NOTES AND BONDS OF SPECIFIED MATURITIES

[In percent]

3-year	5-year	7-year	10-year	20-year	30-year
0.9	1.6	1.9	2.4	2.9	2.7

Analyses of programs with terms different from those presented above may use a linear interpolation. For example, a four-year project can be evaluated with a rate equal to the average of the three-year and five-year rates. Programs with durations longer than 30 years may use the 30-year interest rate.

[FR Doc. E8-30793 Filed 12-31-08; 8:45 am]

BILLING CODE 3110-01-P

PEACE CORPS

Privacy Act System of Records

AGENCY: Peace Corps.

ACTION: Notice of an amendment to a Privacy Act system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a) the Peace Corps is giving notice of a new system of records, PC-33, titled the Consolidated Incident Reporting System (CIRS).

DATES: This action will be effective without further notice on February 17, 2009 unless comments are received by February 2, 2009 that would result in a contrary determination.

ADDRESSES: You may submit comments by e-mail to nmiller@peacecorps.gov. You may also submit comments by mail to Nancy G. Miller, Office of the General Counsel, Peace Corps, Suite 8200, 1111 20th Street, NW., Washington, DC 20526. Contact Nancy G. Miller for copies of comments.

FOR FURTHER INFORMATION CONTACT: Nancy G. Miller, Associate General Counsel, 202-692-2150, nmiller@peacecorps.gov.

SUPPLEMENTARY INFORMATION: Section 552a provides that the public be given a 30-day period in which to comment on the new system. The Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to review the proposed system. In accordance with 5 U.S.C. 552a, Peace Corps has provided a report on this system to OMB and the Congress.

SYSTEM NAME:

PC-33 Consolidated Incident Reporting System (CIRS).

SECURITY CLASSIFICATION:

Not applicable.

SYSTEM LOCATION:

Office of the Chief Information Officer and the Office of Safety and Security, Peace Corps, 1111 20th St., NW., Washington, DC 20526, as well as Peace Corps overseas offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Peace Corps Volunteers, Trainees, Peace Corps Response Volunteers, alleged offenders, and witnesses.

CATEGORIES OF RECORDS IN THE SYSTEM:

Volunteer name; Volunteer contact information, including phone number, address, and/or e-mail address; Volunteer Tag (system-generated ID associated with the Volunteer's name); race/ethnicity; sex; country of incident; country of service; sector of assignment; marital status; age; Volunteer site; type of incident; date of incident; date incident was reported to post; time of incident; personnel notified; incident location; size of population of community (i.e., urban, intermediate, rural); nature and details of the incident; alcohol use by Volunteer at time of incident; weapon use by alleged offender; injury sustained; medical/counseling support provided; victim's intention to prosecute; and alleged offender's motive for committing incident; name of alleged offender; age range of alleged offender; gender of alleged offender; relationship of alleged offender to victim; alcohol use by alleged offender at time of incident; whether alleged offender was apprehended; information on witnesses, such as name and contact information; and post follow up or changes to original incident report, as noted in the updates section.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Peace Corps Act , 22 U.S.C. 2501 *et seq.*

PURPOSE(S):

To provide a single central facility within the Peace Corps for tracking

crimes against Volunteers; analyzing trends; and responding to requests from executive, legislative, and oversight bodies, as well as the public, for statistical crime data relating to criminal and other high-interest incidents. The Peace Corps will use this information for programmatic and training purposes in order to make informed decisions about potential changes in policy and/or programs. The system notifies in a timely manner Peace Corps headquarters and overseas staff who have a need to know when a crime has occurred against a Volunteer. Such staff make safety and security, medical, or management decisions regarding the Volunteer victim. The system also notifies the U.S. Embassy's Regional Security Officers covering the post whenever a crime against a Volunteer occurs so that they may initiate investigative procedures, as necessary.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USERS:

General routine uses A through M apply to this system. In addition to general routine uses, the Peace Corps will use the data collected via the CIRS for programmatic and training purposes and to make informed decisions about potential changes in policy and/or programs.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In a protected database and in a locked file cabinet in a locked room.

RETRIEVABILITY:

Records are retrievable by any, all, or any combination of the following data fields: Volunteer name; contact information; Volunteer Tag; race/ethnicity; sex; country of incident, country of service; sector of assignment; marital status; age; Volunteer site; type of incident; date of incident; date incident was reported; time of incident; date of incident; names of personnel notified; size of population of community; incident location; nature and details of the incident/offense;

alcohol use by Volunteer at time of incident; whether weapons were involved; type of injury; medical support provided; updates to the incident report; victim's intention to prosecute; and motive for committing incident; name of alleged offender; age range of alleged offender; gender of alleged offender; relationship of alleged offender to victim; alcohol use by alleged offender at time of incident; and whether alleged offender was apprehended; any available information on witness.

SAFEGUARDS:

Names and social security numbers have been redacted from paper records that were collected until 2006. After 2006, social security numbers were no longer collected on the Volunteer. The crime incident database does not collect or store previously collected social security numbers. Accounts are created for Peace Corps staff for whom a business need exists, i.e., select staff in Director's office, Safety and Security, Regions, and Volunteer Support. Regional Security Officers and Assistant Regional Security Officers at the U.S. Embassy at post also receive CIRS accounts. Embassy officials must complete a Technology Access Agreement form to receive an account. All CIRS accounts require a user name and password. Access to Volunteer names and addresses in the reports is restricted to only those CIRS users who have a need to know. These include reporting post staff, Office of Volunteer Support staff who are responsible for medical support, and Regional Security Officers with the U.S. Embassy.

Information is encrypted using 128-bit SSL and AES encryptions standards. The system platform went through the accreditation process in February 2008 (i.e., accreditation with the WebTrust seal) and through a SAS-70 Type II audit performed by a third party auditor.

RETENTION AND DISPOSAL:

As there is no records disposal schedule for this information, electronic and paper records are being retained indefinitely. Records are retained to allow for historical data and trends analysis. Paper files are redacted to remove Volunteer names and social security numbers. The annual Safety of the Volunteer report is kept on file permanently for historical reference.

SYSTEM MANAGER(S) AND ADDRESS:

Social Science Analyst, Office Safety and Security, Peace Corps, 1111 20th St., NW., Washington, DC 20526.

NOTIFICATION PROCEDURE:

Any individual who wants notification that this system of records contains a record about him or her should make a written request to the System Manager. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card, or other identifying documentation. Additional identification may be required in some instances. Complete Peace Corps Privacy Act procedures are set out in 22 CFR Part 308.

RECORD ACCESS PROCEDURES:

Any individual who wants access to his or her record should make a written request to the System Manager. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card, or other identifying documentation. Additional identification may be required in some instances. Complete Peace Corps Privacy Act procedures are set out in 22 CFR Part 308.

CONTESTING RECORD PROCEDURES:

Any individual who wants to contest the contents of a record should make a written request to the System Manager. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card, or other identifying documentation. Additional identification may be required in some instances. Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete Peace Corps Privacy Act procedures are set out in 22 CFR Part 308.

RECORD SOURCE CATEGORIES:

Record Subject.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: December 23, 2008.

Carl R. Sosebee,

Acting General Counsel.

[FR Doc. E8-31221 Filed 12-31-08; 8:45 am]

BILLING CODE 6015-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59162; File No. 4-533]

Joint Industry Plan; Notice of Filing and Immediate Effectiveness of Amendments to the National Market System Plan for the Selection and Reservation of Securities Symbols To Add New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Alternext US LLC and Chicago Board Options Exchange, Incorporated as Parties Thereto

December 24, 2008.

Pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 608 thereunder,² notice is hereby given that on December 22, 2008, (i) New York Stock Exchange LLC ("NYSE"), NYSE Arca, Inc. ("NYSE Arca"), and NYSE Alternext U.S. LLC ("NYSE Alternext" and, together with NYSE and NYSE Arca, the "NYSE Group Exchanges") and (ii) Chicago Board Options Exchange, Incorporated ("CBOE") filed with the Securities and Exchange Commission ("Commission") amendments to the National Market System Plan for the Selection and Reservation of Securities Symbols ("Symbology Plan" or "Plan").³ The amendments propose to add the NYSE Group Exchanges and CBOE as parties to the Symbology Plan. The Commission is publishing this notice to solicit comments on the proposed amendment from interested persons.

I. Description and Purpose of the Amendment

The current parties to the Symbology Plan are CHX, FINRA, the International Securities Exchange, LLC ("ISE"),⁴ Nasdaq, NSX and Phlx. The proposed amendments to the Symbology Plan would add the NYSE Group Exchanges and CBOE parties to the Symbology Plan. A self-regulatory organization ("SRO") may become a party to the Symbology Plan if it satisfies the

¹ 15 U.S.C. 78k-1(a)(3).

² 17 CFR 242.608.

³ On November 6, 2008, the Commission approved the Symbology Plan that was originally proposed by the Chicago Stock Exchange, Inc. ("CHX"), The Nasdaq Stock Market, Inc. ("Nasdaq"), National Association of Securities Dealers, Inc. ("NASD") (n/k/a Financial Industry Regulatory Authority, Inc. ("FINRA")),⁴ National Stock Exchange, Inc. ("NSX"), and Philadelphia Stock Exchange, Inc. ("Phlx"), subject to certain changes. See Securities Exchange Act Release No. 58904, 73 FR 67218 (November 13, 2008) (File No. 4-533).

⁴ On November 18, 2008, ISE filed with the Commission an amendment to the Plan to add ISE as a member to the Plan. See Securities Exchange Act Release No. 59024 (November 26, 2008), 73 FR 74538 (December 8, 2008) (File No. 4-533).

requirements of Section I(c) of the Plan. Specifically, an SRO may become a party to the Symbology Plan if: (i) It maintains a market for the listing or trading of Plan Securities,⁵ in accordance with rules approved by the Commission, which securities are identified by one, two, or three character symbols, on the one hand, or four or five character symbols, on the other hand, in each case prior to any suffix or special conditional identifier; (ii) it signs a current copy of the Plan; and (iii) it pays to the other parties a proportionate share of the aggregate development costs, based upon the number of symbols reserved by the new party during the first twelve (12) months of such party's membership.⁶

The NYSE Group Exchanges and CBOE have submitted a signed copy of the Symbology Plan to the Commission in accordance with the requirement set forth in the Symbology Plan regarding new parties to the plan.

II. Effectiveness of the Proposed Symbology Plan Amendment

The foregoing proposed Symbology Plan amendments have become effective pursuant to Rule 608(b)(3)(iii)⁷ because it involves solely technical or ministerial matters. At any time within sixty days of the filing of these amendments, the Commission may summarily abrogate the amendment and require that it be refiled pursuant to paragraph (b)(1) of Rule 608,⁸ if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether these amendments are 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

⁵ "Plan Securities" are defined in the Symbology Plan as securities that: (i) Are NMS securities as currently defined in Rule 600(a)(46) under the Act; and (ii) any other equity securities quoted, traded and/or trade reported through an SRO facility.

⁶ Sections I(c) and IV(a) of the Plan.

⁷ 17 CFR 242.608(b)(3)(iii).

⁸ 17 CFR 242.608(b)(1).

- Send an e-mail to rule-comments@sec.gov. Please include File Number 4-533 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 4-533. 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 4-533 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31205 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59165; File No. S7-35-08]

Order Pursuant to Section 36 of the Securities Exchange Act of 1934 Granting Temporary Exemptions From Sections 5 and 6 of the Exchange Act for Broker-Dealers and Exchanges Effecting Transactions in Credit Default Swaps

December 24, 2008.

I. Background

In response to the recent turmoil in the financial markets, the Securities and Exchange Commission ("Commission") has taken multiple actions to protect investors and ensure the integrity of the nation's securities markets.¹ Today, we are taking further action designed to address concerns related to the market in credit default swaps ("CDS"). The over-the-counter ("OTC") market for CDS has been a source of concerns to us and other financial regulators. These concerns include the systemic risk posed by CDS, highlighted by the possible inability of parties to meet their obligations as counterparties and the potential resulting adverse effects on

¹ A nonexclusive list of the Commission's actions to stabilize financial markets during this credit crisis includes: Adopting a package of measures to strengthen investor protections against naked short selling, including rules requiring a hard T+3 close-out, eliminating the options market maker exception of Regulation SHO, and expressly targeting fraud in short selling transactions (*See* Securities Exchange Act Release No. 58572 (September 17, 2008), 73 FR 54875 (September 23, 2008)); issuing an emergency order to enhance protections against naked short selling in the securities of primary dealers, Fannie Mae, and Freddie Mac (*See* Securities Exchange Act Release No. 58166 (July 15, 2008), 73 FR 42379 (July 21, 2008)); taking temporary emergency action to ban short selling in financial securities (*See* Securities Exchange Act Release No. 58592 (September 18, 2008), 73 FR 55169 (September 24, 2008)); approving emergency rulemaking to ensure disclosure of short positions by hedge funds and other institutional money managers (*See* Securities Exchange Act Release No. 58591A (September 21, 2008), 73 FR 55557 (September 25, 2008)); proposing rules to strengthen the regulation of credit rating agencies and making the limits and purposes of credit ratings clearer to investors (*See* Securities Exchange Act Release No. 57967 (June 16, 2008), 73 FR 36212 (June 25, 2008)); entering into a Memorandum of Understanding with the Board of Governors of the Federal Reserve System ("FRB") to make sure key federal financial regulators share information and coordinate regulatory activities in important areas of common interest (*See* Memorandum of Understanding Between the U.S. Securities and Exchange Commission and the Board of Governors of the Federal Reserve System Regarding Coordination and Information Sharing in Areas of Common Regulatory and Supervisory Interest (July 7, 2008), http://www.sec.gov/news/press/2008/2008-134_mou.pdf).

⁹ 17 CFR 200.30-3(a)(12).

other markets and the financial system.² Recent credit market events have demonstrated the seriousness of these risks in a CDS market operating without meaningful regulation, transparency,³ or central counterparties (“CCPs”).⁴ These events have emphasized the need for CCPs as mechanisms to help control such risks.⁵ A CCP for CDS could be an important step in reducing the counterparty risks inherent in the CDS market, and thereby help mitigate potential systemic impacts. In November 2008, the President’s Working Group on Financial Markets stated that the implementation of a CCP for CDS was a top priority⁶ and, in furtherance of this recommendation, the Commission, the FRB and the Commodity Futures Trading Commission (“CFTC”) signed a Memorandum of Understanding⁷ that establishes a framework for consultation and information sharing on issues related to CCPs for CDS. Given the continued uncertainty in this market, taking action to help foster the prompt development of CCPs, including granting conditional exemptions from certain provisions of the federal securities laws, is in the public interest.

A CDS is a bilateral contract between two parties, known as counterparties. The value of this financial contract is based on underlying obligations (“reference obligations”) of a single

entity (a “reference entity”) or on a particular security or other debt obligation (“reference security”), or an index of several such entities, securities, or obligations. The obligation of a seller under a CDS to make payments under a CDS contract is triggered by a default or other credit event as to such entity or entities or such security or securities. Investors may use CDS for a variety of reasons, including to offset or insure against risk in their fixed-income portfolios, to take positions in bonds or in segments of the debt market as represented by an index, or to capitalize on the volatility in credit spreads during times of economic uncertainty. In recent years, CDS market volumes have rapidly increased.⁸ This growth has coincided with a significant rise in the types and number of entities participating in the CDS market.⁹

The Commission’s authority over this OTC market for CDS is limited. Specifically, section 3A of the Securities Exchange Act of 1934 (“Exchange Act”) limits the Commission’s authority over swap agreements, as defined in section 206A of the Gramm-Leach-Bliley Act.¹⁰ For those CDS that are swap agreements, the exclusion from the definition of security in section 3A of the Exchange Act, and related provisions, will continue to apply. The Commission’s action today does not affect these CDS, and this order does not apply to them. For those CDS that are not swap agreements (“non-excluded CDS”), the Commission’s action today provides certain exemptions to exchanges that effect transactions in such non-excluded CDS and to brokers and dealers that effect transactions in non-excluded CDS on exchanges, and is designed to facilitate the development of one or more CDS exchanges.¹¹

In companion actions today, the Commission is temporarily exempting, subject to conditions, LCH.Clearnet Ltd. from the requirement to register as a clearing agency under section 17A of the Exchange Act solely to perform the functions of a clearing agency for non-excluded CDS transactions.¹² To facilitate the operation of one or more CCPs for the CDS market, the Commission has also approved interim final temporary rules providing exemptions under the Securities Act of 1933 and Exchange Act for non-excluded CDS.

In conjunction with these exemptions, the Commission in this order is providing a temporary exemption to any exchange that effects or reports transactions in non-excluded CDS and is not otherwise subject to the requirements under Sections 5 and 6 of the Exchange Act¹³ from the requirement to register as a national securities exchange, and to any broker or dealer that effects or reports transactions in non-excluded CDS on such an exempt exchange.¹⁴ The

CDS, proposed by the Chicago Board Options Exchange, were securities because they are options based on the value of a security or securities, options on an interest in a security or securities, or options based on the value of an interest in a security or securities. See Securities Exchange Act Release No. 55871 (June 6, 2007), 72 FR 32372, 32375–77 (June 12, 2007) (File No. SR-CBOE-2006-84) (“CBOE CDO Order”); Securities Exchange Act Release No. 56275 (August 17, 2007), 72 FR 47297 (August 22, 2008) (File No. SR-CBOE-2007-26) (together with the CBOE CDO Order, the “CBOE Orders”). The Commission made special note that, “because credit default options will be exchange-traded and not individually negotiated, * * * they are not qualifying swap agreements under Section 206A of the Gramm-Leach-Bliley Act, * * * and, therefore, not excluded from the definition of security by Section 3A of the Exchange Act.” 72 FR at 32376 n. 39. Unlike the options at issue in the CBOE Orders, which had fixed payouts in the event of a default or other credit event, the CDS that are the subject of the Commission’s actions today may provide for the delivery of a debt security or securities against a specified amount, or a cash payment based on the value of a debt security or securities. For those CDS that are not qualifying swap agreements, that have payouts tied to the delivery of debt securities, or that are based on the value of debt securities, there may be arguments in addition to those in the CBOE Orders that such CDS are security options.

¹² See Securities Exchange Act Release No. 59164 (December 24, 2008) (File No. S7-34-08).

¹³ 15 U.S.C. 78e and 78f.

¹⁴ A national securities exchange that effects transactions in CDS would continue to be required to comply with all requirements under the Exchange Act applicable to such transactions. A national securities exchange could form subsidiaries or affiliates that operate exchanges exempt under this order. Any subsidiary or affiliate of a registered exchange could not integrate, or otherwise link, the exempt CDS exchange with the registered exchange, including the premises or property of such exchange for effecting or reporting a transaction, without being considered a “facility of the exchange.” See Section 3(a)(2) of the Exchange Act, 15 U.S.C. 78c(a)(2).

² In addition to the potential systemic risks that CDS pose to financial stability, we are concerned about other potential risks in this market, including operational risks, risks relating to manipulation and fraud, and regulatory arbitrage risks.

³ See Policy Objectives for the OTC Derivatives Market, The President’s Working Group on Financial Markets (November 14, 2008), <http://www.ustreas.gov/press/releases/reports/policyobjectives.pdf> (“Public reporting of prices, trading volumes and aggregate open interest should be required to increase market transparency for participants and the public.”).

⁴ See The Role of Credit Derivatives in the U.S. Economy Before the H. Agric. Comm., 110th Cong. (2008) (Statement of Erik Sirri, Director of the Division of Trading and Markets, Commission).

⁵ See *id.*

⁶ See Policy Objectives for the OTC Derivatives Market, The President’s Working Group on Financial Markets (November 14, 2008), <http://www.ustreas.gov/press/releases/reports/policyobjectives.pdf>. See also Policy Statement on Financial Market Developments, The President’s Working Group on Financial Markets (March 13, 2008), http://www.treas.gov/press/releases/reports/pwgpolicystatementkturmoil_03122008.pdf; Progress Update on March Policy Statement on Financial Market Developments, The President’s Working Group on Financial Markets (October 2008), <http://www.treas.gov/press/releases/reports/q4progress%20update.pdf>.

⁷ See Memorandum of Understanding Between the Board of Governors of the Federal Reserve System, the U.S. Commodity Futures Trading Commission and the U.S. Securities and Exchange Commission Regarding Central Counterparties for Credit Default Swaps (November 14, 2008), <http://www.treas.gov/press/releases/reports/finalmou.pdf>.

⁸ See Semiannual OTC derivatives statistics at end-December 2007, Bank for International Settlements (“BIS”), <http://www.bis.org/statistics/otcder/dt1920a.pdf>.

⁹ CDS were initially created to meet the demand of banking institutions looking to hedge and diversify the credit risk attendant with their lending activities. However, financial institutions such as insurance companies, pension funds, securities firms, and hedge funds have entered the CDS market.

¹⁰ 15 U.S.C. 78c-1. Section 3A excludes both a non-security-based and a security-based swap agreement from the definition of “security” under Section 3(a)(10) of the Exchange Act, 15 U.S.C. 78c(a)(10). Section 206A of the Gramm-Leach-Bliley Act defines a “swap agreement” as “any agreement, contract, or transaction between eligible contract participants (as defined in section 1a(12) of the Commodity Exchange Act* * * * * the material terms of which (other than price and quantity) are subject to individual negotiation.” 15 U.S.C. 78c note.

¹¹ The Commission found that credit default options and credit default basket options, which are essentially exchange-traded equivalents of OTC

exemptions in this order are subject to the conditions discussed below.

The Commission believes that the CDS market would benefit from the development of exchanges for non-excluded CDS. As the Commission has previously noted when approving a proposed rule change by the Chicago Board Options Exchange to list and trade certain CDS contracts, there are several benefits to trading such products on exchanges rather than over-the-counter.¹⁵ These benefits include a centralized market, standardized contract specifications, transparent quotations, and transaction reporting.¹⁶ Exchange trading would permit real-time matching of orders, and enhance transparency of the CDS market by promoting dissemination of pre-trade quotations as well as post-trade transaction information. Additional pre-trade and post-trade transparency would enable exchange subscribers to better assess market depth and liquidity and allow regulators to better surveil for violations of the securities laws.

Accordingly, the Commission is using its authority under section 36 of the Exchange Act¹⁷ to exempt temporarily any exchange that effects transactions in non-excluded CDS and is not otherwise subject to the requirements under Sections 5 and 6 of the Exchange Act,¹⁸ and the rules and regulations thereunder, from the requirement to register as a national securities exchange under section 6 of the Exchange Act,¹⁹ and from the prohibition in section 5 of the Exchange Act²⁰ against effecting transactions as an exchange unless it is registered as a national securities exchange or exempt from registration due to the limited volume of its transactions. The Commission finds that such action is necessary and appropriate in the public interest and consistent with the protection of investors to facilitate the operation of one or more CDS exchanges in connection with the establishment of one or more CCP that clear and settle non-excluded CDS.²¹ The Commission is also temporarily exempting brokers and dealers from the section 5 prohibition against effecting or reporting transactions in securities otherwise than on a national securities exchange or an exchange that is exempt from registration due to its limited volume.

The conditions to these exemptions will enable to the Commission to oversee the development of CDS exchanges, and to take such additional action as we may deem necessary to promote the public interest and the protection of investors. Moreover, the limited duration of the exemptions provided today will enable one or more CDS exchanges to become operational while we gain experience with the CDS market and evaluate public input, including comments we receive on the temporary exemptions granted in today's order.

II. Discussion

Section 5 of the Exchange Act states that "[i]t shall be unlawful for any broker, dealer, or exchange, directly or indirectly, to make use of the mails or any means or instrumentality of interstate commerce for the purpose of using any facility of an exchange * * * to effect any transaction in a security, or to report any such transactions, unless such exchange (1) is registered as a national securities exchange under section 6 of [the Exchange Act], or (2) is exempted from such registration * * * by reason of the limited volume of transactions effected on such exchange* * *." ²² Section 6 of the Exchange Act sets forth a procedure whereby an exchange²³ may register as a national securities exchange.²⁴

Section 36 of the Exchange Act provides that the Commission, "by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of [the Exchange Act] or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors." To facilitate the establishment of one or more exchanges for non-excluded CDS, the Commission is exercising its authority under section 36 of the Exchange Act to temporarily exempt any exchange, broker or dealer that effects transactions in non-excluded CDS from the prohibition in Section 5 of the Exchange Act and (in the case of

exchanges) the requirements in Section 6 of the Exchange Act and the rules and regulations thereunder. These temporary exemptions are subject to certain conditions, discussed further below. These conditions on exchanges generally mirror those applicable to alternative trading systems, which are securities trading systems that the Commission previously exempted from exchange registration.²⁵

This temporary exemption is designed to allow brokers, dealers, and exchanges to effect transactions in non-excluded CDS on exchanges, subject to certain conditions. The Commission believes the exemption, together with the conditions, is necessary in the public interest and consistent with the protection of investors. In addition, the Commission believes that these conditions will not impede the ability of brokers, dealers, and exchanges to compete in the market for CDS. The limited term of this exemption will provide the Commission with adequate time to evaluate the application of this exemption to non-excluded CDS exchanges, and whether such conditions should be modified. In particular, the Commission will be considering whether Regulation ATS, with or without modifications, could apply to systems that match orders in non-excluded CDS of multiple buyers and sellers.

This temporary exemption is available only to exchanges that effect transactions in non-excluded CDS. To the extent that an exchange is otherwise subject to the requirements of section 5 of the Exchange Act, it must register with the Commission as a national securities exchange under Section 6 of the Exchange Act and the rules and regulations thereunder or comply with the terms of another exemption. Similarly, a broker or dealer is temporarily exempt from the prohibition in Section 5 only to the extent that it effects transactions in non-

²⁵ See Regulation ATS, 17 CFR 242.300 *et seq.* In 1998, the Commission exercised its exemptive authority under Section 36 of the Exchange Act and its general authority under Section 11A of the Exchange Act, 15 U.S.C. 78k-1, to establish a regulatory framework for "alternative trading systems," which perform many of the same functions as exchanges. Under this framework, an entity that, like an exchange, matches the orders in securities of multiple buyers and sellers according to established, non-discretionary methods is exempt from the definition of "exchange" if it instead registers as a broker-dealer and complies with Regulation ATS. Regulation ATS is designed, among other things, "to adopt a regulatory framework that addresses [the Commission's] concerns without jeopardizing the commercial viability of these markets." Regulation ATS Adopting Release, *supra* note 23, 63 FR at 70846.

²² 15 U.S.C. 78e.

²³ Section 3(a)(1) of the Exchange Act, 15 U.S.C. 78c(a)(1), defines "exchange." Rule 3b-16 under the Exchange Act, 17 CFR 240.3b-16, defines certain terms used in the statutory definition of exchange. See Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844 (December 22, 1998) ("Regulation ATS Adopting Release") (adopting Rule 3b-16 in addition to Regulation ATS).

²⁴ 15 U.S.C. 78f. Section 6 of the Exchange Act also sets forth various requirements to which a national securities exchange is subject.

¹⁵ See CBOE Orders, *supra* note 11.

¹⁶ *Id.*

¹⁷ 15 U.S.C. 78mm.

¹⁸ 15 U.S.C. 78e and 78f.

¹⁹ 15 U.S.C. 78f.

²⁰ 15 U.S.C. 78e.

²¹ See *supra* note 12.

excluded CDS on an exchange or reports such transactions on an exchange.

The Commission believes that this order will facilitate the establishment of one or more exchanges that effect transactions in non-excluded CDS. For this reason and the reasons discussed above,²⁶ the Commission believes that these exemptions are necessary or appropriate in the public interest and consistent with the protection of investors.

As noted, the conditions under which CDS exchanges must operate to qualify for the exemption from exchange registration being granted today are modeled on requirements applicable to alternative trading systems. Like an alternative trading system, a CDS exchange must keep records about its operations, its subscribers, and their orders.²⁷ A CDS exchange also must provide the Commission with trading information on a quarterly basis²⁸ and establish procedures to ensure the confidential treatment of trading information.²⁹ Likewise, a CDS exchange must permit the Commission to examine its premises, systems, and records and must cooperate with the examination of its subscribers.³⁰ These requirements are designed to allow the Commission to monitor market developments, to ascertain how new entrants are affecting the national market system, and to promote compliance with the federal securities laws generally. The Commission believes that temporarily exempting exchanges that effect transactions in non-excluded CDS from exchange registration, subject to these conditions, is necessary or appropriate in the public interest and is consistent with the protection of investors.

A. Exemption From Sections 5 and 6 of the Exchange Act for Exchanges

1. No Self-Regulatory Authority

To be exempt under this order, the exchange must not: (a) Set rules governing the conduct of subscribers other than the conduct of such subscribers trading on such exchange; or (b) discipline subscribers under the Exchange Act other than by exclusion from trading. That is, an exempted exchange may not exercise self-regulatory authority over its subscribers. The Commission intends this condition to be the same requirement as applies to alternative trading systems under

Regulation ATS. As described in the Regulation ATS Adopting Release, self-regulatory authority would include, for example, any restrictions on subscribers' activities outside of the exchange or imposing as a condition of participation any requirement for which the exchange would examine subscribers for compliance. The requirement in Regulation ATS and this condition are based on the Commission's belief that a organization, association, or group of persons that could exercise self-regulatory authority over its subscribers should be registered as a self-regulatory organization ("SRO") and subject to the full responsibilities and supervision that registration entails. The Commission continues to believe that rules governing exchange subscriber conduct may be imposed and enforced only by SROs because of the potential that they may be applied for anti-competitive purposes. However, as we noted in connection with adopting Regulation ATS, the Commission does not intend this condition to preclude a trading system from applying credit standards to its subscribers or requiring subscribers to provide financial information relevant to their activity on the system.³¹

2. Recordkeeping

In addition, to be exempt under this order, an exchange must maintain an audit trail of orders that it receives and transactions that it effects. These records are critical to the Commission's ability to oversee the CDS market, detect and deter illicit market activity, and take action as necessary to address manipulation and fraud, including insider trading. These recordkeeping and record preservation requirements are comparable to those required under Regulation ATS and tailored to apply to non-excluded CDS.³² Specifically, an exchange must make and keep the following records for a period of not less than three years, the first two years in an easily accessible place:

- A record of subscribers in the exchange (identifying any affiliations between the exchange and subscribers in the exchange, including common directors, officers, or owners);
- Daily summaries of trading, including: (a) Information identifying CDS in which transactions are effected; and (b) transaction volume, expressed in terms of number of trades and total U.S. dollar notional value;

- Time-sequenced records of order information, including: (a) Identity of the party entering an order; (b) identification of non-excluded CDS contract (including the reference entity, security, or index, and notional value); (c) date and time that order was received; (d) price (whether expressed as credit spread, rate, strike, or coupon); (e) whether the order is to buy or sell and any order conditions; (f) any subsequent modification or cancellation of the order; (g) date and time the order was executed, the size (e.g., notional value amount) executed, and the price; and (h) identity of the parties to the transaction.³³

In addition, as a condition of this exemption, an exchange must preserve the following records:

- For a period of not less than three years, the first two years in an easily accessible place, all notices provided by such exchange to subscribers generally, whether written or communicated through automated means, including, but not limited to, notices addressing hours of system operations, system malfunctions, changes to system procedures, maintenance of hardware and software, instructions pertaining to access to the market and denials of, or limitations on, access to the exchange; and

- During the life of the enterprise and of any successor enterprise, the exchange's organizational documents and copies of reports filed with the Commission pursuant to this exemption.

An exchange exempt pursuant to this order may comply with these recordkeeping and record preservation requirements through use of a service bureau, depository, or other recordkeeping service that maintains and preserves these records on behalf of the exchange. An agreement with a service bureau, depository, or other recordkeeping service will not relieve the exchange from the responsibility to prepare and maintain the specified records.

³³ These information items, with one exception, must be recorded and kept current by alternative trading systems pursuant to Regulation ATS. See 17 CFR 242.301(b)(8) and 242.302(c). Alternative trading systems are not required by Regulation ATS to keep records of the identity of the party entering an order. The Commission believes, however, that such information could be important to its ability to enforce the securities laws and is, therefore, to be kept as a condition to this exemption. Alternative trading systems must be registered with the Commission as a broker-dealer, and are therefore subject to additional Commission recordkeeping rules. See 17 CFR 242.301(b)(1). An exchange that avails itself of this exemption, however, may not otherwise be subject to requirements under the Exchange Act.

²⁶ See *supra* notes 15–16 and accompanying text.

²⁷ Compare 17 CFR 242.301(b)(8), 242.302, and 242.303.

²⁸ Compare 17 CFR 242.301(b)(9).

²⁹ Compare 17 CFR 242.301(b)(10).

³⁰ Compare 17 CFR 242.301(b)(7).

³¹ See Regulation ATS Adopting Release, *supra* note 23, 63 FR at 70859.

³² See 17 CFR 242.301(b)(8), 242.302, and 242.303.

The Commission believes that the types of records an exchange would be required to make and keep pursuant to this condition are records an exchange would keep in the normal course of its business and, therefore, that this condition is not unduly burdensome.

3. Regulatory Reporting

An exchange that relies on this order must, within five days of commencing operation, submit a notice to the Commission³⁴ that includes the following information:

1. Full legal name of the exchange;
2. A description of the exchange's ownership structure;
3. Contact person and contact information;
4. A general description of the CDS contracts that trade on the exchange; and
5. A description of how the exchange operates.

This information is essential for the Commission to understand developments in the CDS market. Any subsequent action regarding this exemption—for example, whether it should be modified, extended, or allowed to expire—is predicated on understanding which market participants are relying on it. In the future, different regulatory frameworks may be appropriate for different market participants. These notices will enable the Commission to commence a dialog with the relevant market participants.

In addition, an exchange that relies on this exemption must report the following information to the Commission within 30 days of the end of each quarter:

1. The total dollar volume of transactions executed during the quarter, broken down by reference entity, security, or index;
2. The total unit volume and/or notional amount executed during the quarter, broken down by reference entity, security, or index; and
3. A list of all subscribers that effected transactions on the exchange during the quarter.

Reporting of this information will assist the Commission in carrying out its responsibility to supervise and regulate the securities markets. This information is similar to that which an alternative trading system must provide quarterly.³⁵

³⁴ Any such notice should be sent to: Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549, and be noted as regarding "CDS Exchange Exemption from Registration."

³⁵ See 17 CFR 242.301(b)(9)(i); Form ATS-R, 17 CFR 249.638. The Commission notes that an

4. Confidentiality of Trading Information

An exchange relying on this order also must establish adequate safeguards and procedures to protect subscribers' confidential trading information. Such safeguards and procedures shall include: (a) Limiting access to the confidential trading information of subscribers to those employees of the exchange who are operating the system or responsible for its compliance with this exemption or any other applicable rules; and (b) implementing standards controlling employees of the exchange trading for their own accounts. The exchange must adopt and implement adequate oversight procedures to ensure that the safeguards and procedures established pursuant to this condition are followed. This condition, which closely tracks a requirement applicable to alternative trading systems,³⁶ is designed to prevent the misuse of subscriber trading information that is available to the exchange. This should strengthen confidence in the exchange, promoting participation.

5. Commission Jurisdiction

Finally, an exchange that relies on this order must provide access to the Commission to conduct on-site inspections of its facilities (including automated systems and systems environment), records, and personnel related to exchange activities. The exchange must cooperate with the Commission in connection with the investigation of any exchange subscribers. This requirement is similar to one in Regulation ATS that applies to alternative trading systems.³⁷

Recent market events have clearly demonstrated the importance of the CDS market and its potential to impact other markets, including the equity securities markets. It is therefore imperative that the Commission have examination authority over any exchange that effects transactions in non-excluded CDS, with regard to its compliance with the conditions of the exemption provided

alternative trading system is not required to report to the Commission its transaction volume by security; only aggregate volumes must be reported to the Commission. Reports in most equity securities and many debt securities traded on an ATS are required to be reported to an SRO on a transaction-by-transaction basis. This is not the case for CDS. For this reason, the Commission is conditioning this exemption on an exchange providing quarterly information to the Commission on trading volume broken down by reference entity, security, or index. The Commission believes it is appropriate to require this more specific information from CDS exchanges to better understand the development of the exchange-traded market in non-excluded CDS.

³⁶ See 17 CFR 242.301(b)(10).

³⁷ See 17 CFR 242.301(b)(7).

under this order as well as enforcement of the antifraud provisions of the securities laws, including the prohibitions on insider trading. Particularly because the CDS market is so large and involves many market participants that are not directly subject to the Commission's authority, cooperation by the CDS exchange with the Commission in any investigation or enforcement action is crucial.

B. Exemption From Section 5 of the Exchange Act for Brokers and Dealers

Absent an exemption, section 5 of the Exchange Act³⁸ would prohibit brokers and dealers from effecting transactions in non-excluded CDS on an exchange that is not a national securities exchange because of that exchange's reliance on this order. The Commission finds that temporarily exempting brokers and dealers that effect transactions in non-excluded CDS on such an exchange from this restriction in section 5 is necessary and appropriate in the public interest and is consistent with the protection of investors because it will facilitate brokers' and dealers' use of CDS exchanges, which for the reasons noted above the Commission believes would be beneficial. Without also exempting brokers and dealers from this section 5 requirement, the Commission's temporary exemption of CDS exchanges would be ineffective, because brokers and dealers would not be permitted to effect transactions on those exchanges.

Section 5 of the Exchange Act recognizes that there are situations where brokers and dealers should be permitted to trade on an exchange that is not registered as a national securities exchange. Section 5 provides in relevant part that brokers and dealers may effect transactions on an exchange that the Commission, by reason of the limited volume of transactions effected on such exchange, has exempted from registration under Section 6. Brokers and dealers are also permitted to effect transactions on alternative trading systems, which are exempted from the definition of "exchange" and thus do not fall within the restriction of Section 5. For the reasons noted above, the Commission finds that it is consistent with the public interest and the protection of investors to grant a temporary exemption from section 5 of the Exchange Act to any broker or dealer that effects transactions in non-excluded CDS, or reports such transactions, on an exchange that is exempted pursuant to this order.

³⁸ 15 U.S.C. 78e.

C. Solicitation of Comments

The Commission intends to monitor closely the development of the CDS market and intends to determine to what extent, if any, additional regulatory action may be necessary. For example, as circumstances warrant, certain conditions could be added, altered, or eliminated. Moreover, because this exemption is temporary, the Commission will in the future consider whether it should be extended or allowed to expire. The Commission believes it would be prudent to solicit public comment on its action today, and what action it should take with respect to the CDS market in the future. The Commission is soliciting public comment on all aspects of this exemption, including:

1. Whether the length of this temporary exemption (until September 25, 2009) is appropriate. If not, what should the appropriate duration be?
2. Whether the conditions to the exemption are appropriate. Why or why not? Should other conditions apply? Are any of the present conditions to the exemption provided in this order unnecessary? If so, please specify and explain why such conditions are not needed.
3. Whether exchanges relying on this exemption should ultimately be required to register under the Exchange Act. Why or why not?
4. Whether exchanges for non-excluded CDS can reasonably comply with Regulation ATS. Why or why not? If not, what aspects or conditions of Regulation ATS are problematic? Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/other.shtml>);
- Send an e-mail to rule-comments@sec.gov. Please include File Number S7-35-08 on the subject line; or
- Use the Federal eRulemaking Portal (<http://www.regulations.gov/>). Follow the instructions for submitting comments.

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 S7-35-08. This file number should be included on the subject line if e-mail is used. To help us 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/other.shtml>). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

III. Conclusion

It is hereby ordered pursuant to section 36 of the Exchange Act that until September 25, 2009, an exchange is exempt from the requirements of sections 5 and 6 of the Exchange Act³⁹ and the rules and regulations thereunder to the extent that such exchange effects or reports transactions in non-excluded CDS and is not otherwise required to register as a national securities exchange, subject to the following conditions:

- (1) The exchange must not: (a) Set rules governing the conduct of subscribers other than the conduct of such subscribers trading on such exchange; or (b) discipline subscribers other than by exclusion from trading;
- (2) The exchange must make and keep for a period of not less than three years, the first two years in an easily accessible place, the following records:
 - A record of subscribers in the exchange (identifying any affiliations between the exchange and subscribers in the exchange, including common directors, officers, or owners);
 - Daily summaries of trading, including (a) information identifying CDS in which transactions are effected; and (b) transaction volume, expressed in terms of number of trades and total U.S. dollar notional value;
 - Time-sequenced records of order information, including: (a) Identity of the party entering an order; (b) identification of non-excluded CDS contract (including the reference entity, security, or index, and notional value); (c) date and time that order was received; (d) price (whether expressed as credit spread, rate, strike, or coupon); (e) whether the order is to buy or sell and any order conditions; (f) any subsequent modification or cancellation of the order; (g) date and time the order was executed, the size (e.g., notional value amount) executed, and the price; and (h) identity of the parties to the transaction;

(3) The exchange must preserve the following records:

- For a period of not less than three years, the first two years in an easily accessible place, all notices provided by such exchange to subscribers generally, whether written or communicated through automated means, including, but not limited to, notices addressing hours of system operations, system malfunctions, changes to system procedures, maintenance of hardware and software, instructions pertaining to access to the market and denials of, or limitations on, access to the exchange; and

- During the life of the enterprise and of any successor enterprise, the exchange's organizational documents and copies of reports filed with the Commission pursuant to this exemption;

(4) An exchange must, within five days of commencing operation, submit a notice to the Commission that includes the following information:

- Full legal name of the exchange;
- A description of the exchange's ownership structure;
- Contact person and contact information;
- A general description of what CDS contracts trade on the exchange; and
- A description of how the exchange operates;

(5) An exchange must report the following information to the Commission within 30 days of the end of each quarter:

- The total dollar volume of transactions executed during the quarter, broken down by reference entity, security, or index;
- The total unit volume and/or notional amount executed during the quarter, broken down by reference entity, security, or index; and
- A list of all subscribers that effected transactions on the exchange during the quarter;

(6) The exchange must establish adequate safeguards and procedures to protect subscribers' confidential trading information. Such safeguards and procedures shall include: (a) Limiting access to the confidential trading information of subscribers to those employees of the exchange who are operating the system or responsible for its compliance with this exemption or any other applicable rules; and (b) implementing standards controlling employees of the exchange trading for their own accounts. The exchange must adopt and implement adequate oversight procedures to ensure that the safeguards and procedures established pursuant to this condition are followed; and

³⁹ 15 U.S.C. 78e and 78f.

(7) The exchange must provide access to the Commission to conduct on-site inspections of its facilities (including automated systems and systems environment), records, and personnel related to exchange activities. The exchange must cooperate with the Commission in connection with the investigation of any exchange subscribers.

It is further ordered pursuant to section 36 of the Exchange Act that until September 25, 2009, a broker or dealer that effects transactions in non-excluded CDS, or reports such transactions, on an exchange that is exempted pursuant to this order is exempt from section 5 of the Exchange Act.

By the Commission.

Florence E. Harmon,
Acting Secretary.

[FR Doc. E8-31190 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59164; File No. S7-34-08]

Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with Request of Liffe Administration and Management and Lch.Clearnet Ltd. Related to Central Clearing of Credit Default Swaps, and Request for Comments

December 24, 2008.

I. Introduction

In response to the recent turmoil in the financial markets, the Securities and Exchange Commission ("Commission") has taken multiple actions to protect investors and ensure the integrity of the nation's securities markets.¹ Today the

¹ A nonexclusive list of the Commission's actions to stabilize financial markets during this credit crisis includes: Adopting a package of measures to strengthen investor protections against naked short selling, including rules requiring a hard T+3 close-out, eliminating the options market maker exception of Regulation SHO, and expressly targeting fraud in short selling transactions (See Securities Exchange Act Release No. 58572 (September 17, 2008), 73 FR 54875 (September 23, 2008)); issuing an emergency order to enhance protections against naked short selling in the securities of primary dealers, Federal National Mortgage Association ("Fannie Mae"), and Federal Home Loan Mortgage Corporation ("Freddie Mac") (See Securities Exchange Act Release No. 58166 (July 15, 2008), 73 FR 42379 (July 21, 2008)); taking temporary emergency action to ban short selling in financial securities (See Securities Exchange Act Release No. 58592 (September 18, 2008), 73 FR 55169 (September 24, 2008)); approving emergency rulemaking to ensure disclosure of short positions by hedge funds and other institutional money managers (See Securities Exchange Act Release No. 58591A (September 21, 2008), 73 FR 55557 (September 25, 2008)); proposing rules to

Commission is taking further action designed to address concerns related to the market in credit default swaps ("CDS"). The over-the-counter ("OTC") market for CDS has been a source of concerns to us and other financial regulators. These concerns include the systemic risk posed by CDS, highlighted by the possible inability of parties to meet their obligations as counterparties and the potential resulting adverse effects on other markets and the financial system.² Recent credit market events have demonstrated the seriousness of these risks in a CDS market operating without meaningful regulation, transparency,³ or central counterparties ("CCPs").⁴ These events have emphasized the need for CCPs as mechanisms to help control such risks.⁵ A CCP for CDS could be an important step in reducing the counterparty risks inherent in the CDS market, and thereby help mitigate potential systemic impacts. In November 2008, the President's Working Group on Financial Markets stated that the implementation of a CCP for CDS was a top priority⁶

strengthen the regulation of credit rating agencies and making the limits and purposes of credit ratings clearer to investors (See Securities Exchange Act Release No. 57967 (June 16, 2008), 73 FR 36212 (June 25, 2008)); entering into a Memorandum of Understanding with the Board of Governors of the Federal Reserve System ("FRB") to make sure key federal financial regulators share information and coordinate regulatory activities in important areas of common interest (See Memorandum of Understanding Between the U.S. Securities and Exchange Commission and the Board of Governors of the Federal Reserve System Regarding Coordination and Information Sharing in Areas of Common Regulatory and Supervisory Interest (July 7, 2008), http://www.sec.gov/news/press/2008/2008-134_mou.pdf).

² In addition to the potential systemic risks that CDS pose to financial stability, we are concerned about other potential risks in this market, including operational risks, risks relating to manipulation and fraud, and regulatory arbitrage risks.

³ See Policy Objectives for the OTC Derivatives Market, The President's Working Group on Financial Markets, November 14, 2008, available at <http://www.ustreas.gov/press/releases/reports/policyobjectives.pdf> ("Public reporting of prices, trading volumes and aggregate open interest should be required to increase market transparency for participants and the public.").

⁴ See The Role of Credit Derivatives in the U.S. Economy Before the H. Agric. Comm., 110th Cong. (2008) (Statement of Erik Sirri, Director of the Division of Trading and Markets, Commission).

⁵ See *id.*

⁶ See Policy Objectives for the OTC Derivatives Market, The President's Working Group on Financial Markets (November 14, 2008), <http://www.ustreas.gov/press/releases/reports/policyobjectives.pdf>. See also Policy Statement on Financial Market Developments, The President's Working Group on Financial Markets (March 13, 2008), http://www.treas.gov/press/releases/reports/pwgpolicystatementkturmoil_03122008.pdf; Progress Update on March Policy Statement on Financial Market Developments, The President's Working Group on Financial Markets (October 2008), <http://www.treas.gov/press/releases/reports/q4progress%20update.pdf>.

and, in furtherance of this recommendation, the Commission, the FRB and the Commodity Futures Trading Commission ("CFTC") signed a Memorandum of Understanding⁷ that establishes a framework for consultation and information sharing on issues related to CCPs for CDS. Given the continued uncertainty in this market, taking action to help foster the prompt development of CCPs, including granting conditional exemptions from certain provisions of the federal securities laws, is in the public interest.

A CDS is a bilateral contract between two parties, known as counterparties. The value of this financial contract is based on underlying obligations of a single entity or on a particular security or other debt obligation, or an index of several such entities, securities, or obligations. The obligation of a seller under a CDS to make payments under a CDS contract is triggered by a default or other credit event as to such entity or entities or such security or securities. Investors may use CDS for a variety of reasons, including to offset or insure against risk in their fixed-income portfolios, to take positions in bonds or in segments of the debt market as represented by an index, or to capitalize on the volatility in credit spreads during times of economic uncertainty. In recent years, CDS market volumes have rapidly increased.⁸ This growth has coincided with a significant rise in the types and number of entities participating in the CDS market.⁹

The Commission's authority over this OTC market for CDS is limited. Specifically, section 3A of the Securities Exchange Act of 1934 ("Exchange Act") limits the Commission's authority over swap agreements, as defined in section 206A of the Gramm-Leach-Bliley Act.¹⁰

⁷ See Memorandum of Understanding Between the Board of Governors of the Federal Reserve System, the U.S. Commodity Futures Trading Commission and the U.S. Securities and Exchange Commission Regarding Central Counterparties for Credit Default Swaps (November 14, 2008), <http://www.treas.gov/press/releases/reports/finalmou.pdf>.

⁸ See Semiannual OTC derivatives statistics at end-December 2007, Bank for International Settlements ("BIS"), available at <http://www.bis.org/statistics/otcder/dt1920a.pdf>.

⁹ CDS were initially created to meet the demand of banking institutions looking to hedge and diversify the credit risk attendant with their lending activities. However, financial institutions such as insurance companies, pension funds, securities firms, and hedge funds have entered the CDS market.

¹⁰ 15 U.S.C. 78c-1. Section 3A excludes both a non-security-based and a security-based swap agreement from the definition of "security" under Section 3(a)(10) of the Exchange Act, 15 U.S.C. 78c(a)(10). Section 206A of the Gramm-Leach-Bliley Act defines a "swap agreement" as "any agreement, contract, or transaction between eligible contract

Continued

For those CDS that are swap agreements, the exclusion from the definition of security in section 3A of the Exchange Act, and related provisions, will continue to apply. The Commission's action today does not affect these CDS, and this Order does not apply to them. For those CDS that are not swap agreements ("non-excluded CDS"), the Commission's action today provides conditional exemptions from certain requirements of the Exchange Act.

The Commission believes that using well-regulated CCPs to clear transactions in CDS would help promote efficiency and reduce risk in the CDS market and among its participants. These benefits could be particularly significant in times of market stress, as CCPs would mitigate the potential for a market participant's failure to destabilize other market participants, and reduce the effects of misinformation and rumors. CCP-maintained records of CDS transactions would also aid the Commission's efforts to prevent and detect fraud and other abusive market practices.

A well-regulated CCP also would address concerns about counterparty risk by substituting the creditworthiness and liquidity of the CCP for the creditworthiness and liquidity of the counterparties to a CDS. In the absence of a CCP, participants in the OTC CDS market must carefully manage their counterparty risks because the default by a counterparty can render worthless, and payment delay can reduce the usefulness of, the credit protection that has been bought by a CDS purchaser. CDS participants currently attempt to manage counterparty risk by carefully selecting and monitoring their counterparties, entering into legal agreements that permit them to net gains and losses across contracts with a defaulting counterparty, and often requiring counterparty exposures to be collateralized.¹¹ A CCP could allow participants to avoid these risks specific to individual counterparties because a

participants (as defined in section 1a(12) of the Commodity Exchange Act * * * * * the material terms of which (other than price and quantity) are subject to individual negotiation." 15 U.S.C. 78c note.

¹¹ See generally R. Bliss and C. Papanthassiou, "Derivatives clearing, central counterparties and novation: The economic implications" (March 8, 2006), at 6. See also "New Developments in Clearing and Settlement Arrangements for OTC Derivatives," Committee on Payment and Settlement Systems, BIS, at 25 (March 2007), available at <http://www.bis.org/pub/cps77.pdf>; "Reducing Risks and Improving Oversight in the OTC Credit Derivatives Market," Before the Sen. Subcomm. On Secs., Ins. and Investments, 110th Cong. (2008) (Statement of Patrick Parkinson, Deputy Director, Division of Research and Statistics, FRB).

CCP "novates" bilateral trades by entering into separate contractual arrangements with both counterparties—becoming buyer to one and seller to the other.¹² Through novation, it is the CCP that assumes counterparty risks.

For this reason, a CCP for CDS would contribute generally to the goal of market stability. As part of its risk management, a CCP may subject novated contracts to initial and variation margin requirements and establish a clearing fund. The CCP also may implement a loss-sharing arrangement among its participants to respond to a participant insolvency or default.

A CCP would also reduce CDS risks through multilateral netting of trades.¹³ Trades cleared through a CCP would permit market participants to accept the best bid or offer from a dealer in the OTC market with very brief exposure to the creditworthiness of the dealer. In addition, by allowing netting of positions in similar instruments, and netting of gains and losses across different instruments, a CCP would reduce redundant notional exposures and promote the more efficient use of resources for monitoring and managing CDS positions. Through uniform margining and other risk controls, including controls on market-wide concentrations that cannot be implemented effectively when counterparty risk management is decentralized, a CCP can help prevent a single market participant's failure from destabilizing other market participants and, ultimately, the broader financial system.

In this context, LIFFE Administration and Management ("LIFFE A&M") and LCH.Clearnet Ltd. ("LCH.Clearnet") have requested that the Commission grant exemptions from certain requirements under the Exchange Act with respect to their proposed activities in clearing and settling certain index-based CDS, as well as the proposed

¹² "Novation" is a "process through which the original obligation between a buyer and seller is discharged through the substitution of the CCP as seller to buyer and buyer to seller, creating two new contracts." Committee on Payment and Settlement Systems, Technical Committee of the International Organization of Securities Commissioners, *Recommendations for Central Counterparties* (November 2004) at 66.

¹³ See "New Developments in Clearing and Settlement Arrangements for OTC Derivatives," *supra* note 11, at 25. Multilateral netting of trades would permit multiple counterparties to offset their open transaction exposure through the CCP, spreading credit risk across all participants in the clearing system and more effectively diffusing the risk of a counterparty's default than could be accomplished by bilateral netting alone.

activities of certain other persons, as described below.¹⁴

Based on the facts that LIFFE A&M and LCH.Clearnet have presented and the representations they have made,¹⁵ and for the reasons discussed in this Order, the Commission temporarily is exempting, subject to certain conditions, LCH.Clearnet from the requirement to register as a clearing agency under section 17A of the Exchange Act solely to perform the functions of a clearing agency for certain non-excluded CDS transactions. The Commission also temporarily is exempting eligible contract participants and others from certain Exchange Act requirements with respect to non-excluded CDS cleared by LCH.Clearnet. The Commission's exemptions are temporary and will expire on September 25, 2009. To facilitate the operation of one or more CCPs for the CDS market, the Commission has also approved interim final temporary rules providing exemptions under the Securities Act of 1933 and the Exchange Act for non-excluded CDS. Finally, the Commission is providing temporary exemptions in connection with sections 5 and 6 of the Exchange Act for transactions in non-excluded CDS.¹⁶

II. Discussion

A. Description of LIFFE A&M and LCH.Clearnet's Proposal

The exemptive request by LIFFE A&M and LCH.Clearnet describes how their proposed arrangements for central clearing of CDS would operate, and makes representations about the safeguards associated with those arrangements, as described below:

1. LCH Central Counterparty Services for CDS

LIFFE A&M has developed and makes available to its members an OTC derivatives processing service, called Bclear, that will provide a mechanism for the processing and centralized

¹⁴ See Letter from Arthur W. Hahn, KattenMutchinRosenman LLP, to Florence Harmon, Acting Secretary, Commission, December 24, 2008.

¹⁵ See *id.* The exemptions we are granting today are based on representations made by LIFFE A&M and LCH.Clearnet. We recognize, however, that there could be legal uncertainty in the event that one or more of the underlying representations were to become inaccurate. Accordingly, if any of these exemptions were to become unavailable by reason of an underlying representation no longer being materially accurate, the legal status of existing open positions in non-excluded CDS associated with persons subject to those unavailable exemptions would remain unchanged, but no new positions could be established pursuant to the exemptions until all of the underlying representations were again accurate.

¹⁶ See Securities Exchange Act Release No. 59165 (December 24, 2008).

clearing of CDS based on credit default swap indices. The Bclear service processes OTC transactions that are submitted to it by LIFFE A&M members or authorized customers of those members. The Bclear service submits these transactions for clearance to LCH.Clearnet, which stands as the central counterparty to all transactions processed through Bclear.¹⁷ LIFFE A&M will begin processing index CDS through Bclear and would like to make such services available to certain market participants in the U.S. LIFFE A&M represents that the following information regarding index CDS will be available on its Web site (<http://www.nyx.com>): (a) Contract specifications for index CDS that may be processed and cleared through the Bclear Service, and (b) a description of the Bclear Service and rules applicable thereto.

LCH.Clearnet provides CCP services to the following markets and services: London Stock Exchange, SWX Europe Ltd., LIFFE, EDX London, London Metal Exchange, other European Multilateral Trading Facilities (“MTF”), and RepoClear and SwapClear.¹⁸

LIFFE A&M has been granted recognition as a Recognised Investment Exchange under the United Kingdom (“U.K.”) Financial Services and Markets Act 2000 (“FSMA”) by the Financial Services Authority (“FSA”). LCH.Clearnet has been granted recognition as a Recognized Clearing House (“RCH”) under FSMA by the FSA.¹⁹ Regulation and oversight in the

U.K. is carried out by the FSA and the Bank of England. The FSA is the main regulator of LCH.Clearnet as an RCH, while the Bank of England’s oversight is confined to LCH.Clearnet’s payment system.²⁰

The FSA has a regulatory supervision relationship with LIFFE A&M and with LCH.Clearnet. On an annual basis, the FSA undertakes a risk assessment of LIFFE A&M and LCH.Clearnet pursuant to which the FSA determines whether relevant regulatory obligations continue to be met and whether the activities of either LIFFE A&M or LCH.Clearnet pose any risks to the FSA’s statutory objectives, including maintaining market confidence and providing customer protection. The FSA approves the business continuity plans of LCH.Clearnet.

2. CCP Role of LCH.Clearnet in Connection with LIFFE A&M

LIFFE A&M has two categories of members, clearing members and non-clearing members. LIFFE A&M further has two types of clearing members: Individual Clearing Members that clear and settle business for their own account or, in the case of broker-dealers, on behalf of their customers; and General Clearing Members that, in addition, clear and settle business on behalf of other LIFFE A&M members. All transactions of non-clearing members must be cleared through a specific clearing member. All clearing members must also be members of LCH.Clearnet and all are subject to standards of capital adequacy (set by LCH.Clearnet as well as by their respective regulators). Clearing members must also satisfy LIFFE A&M and LCH.Clearnet that they have adequate systems and controls to clear and settle transactions.

The rules of LIFFE A&M provide for members to trade for their own account and/or for their customers, but all transactions must be in the name of the member effecting the trade and that member will be the counterparty for those transactions. Thus, a LIFFE A&M member will be considered to be “acting as principal.” This means that a transaction on LIFFE A&M automatically generates a sequence of matching contracts. For example, a sequence could be between a customer

and a LIFFE A&M member, between that member and a clearing member, and between the clearing member and LCH.Clearnet.

The purpose of the LIFFE A&M rules is to ensure that a party to a transaction need only look to its immediate counterparty for performance and need not concern itself with parties at other points on the contractual chain. Thus, LCH.Clearnet need only look to its clearing members and would have no contractual relationship with, or knowledge of, the non-clearing members of LIFFE A&M or customers on whose behalf the transaction was executed.

Hence, LCH.Clearnet is the CCP to clearing firms each acting as principal in respect of index CDS. Non-clearing members and non-member customers are not party to any contracts registered by clearing members with LCH.Clearnet. Once an index CDS contract has been accepted by LIFFE A&M, a chain of linked contracts is created, all having the same terms. Specifically, the process by which the chain of linked contracts is created is as follows:

a. When a non-member customer enters into an index CDS with or through a non-clearing member, the non-clearing member submits the contract to Bclear. Once LIFFE A&M has accepted the contract, an exchange contract²¹ is created between the non-clearing member, as principal, and its customer. If another customer was originally a counterparty to the index CDS, an exchange contract is created between the non-clearing member, as principal, and the second customer. The contracts are referred to as “customer contracts.” The customer contracts replace the initial index CDS, which ceases to exist at that point.

b. Simultaneously, a matching contract between the non-clearing member and its clearing member, called a “parallel contract,” comes into existence for each of the customer contracts.

c. If the counterparty to the trade is a customer of another non-clearing member, a “related contract” is created between the respective clearing members. The related contract is presented to LCH.Clearnet for registration. If there is a single non-clearing member involved in the transaction, the parallel contracts are presented to LCH.Clearnet for registration.

d. The related contract is replaced by contracts between LCH.Clearnet and the

¹⁷ Bclear provides a means by which counterparties to an index CDS may negotiate a transaction on a bilateral basis and then submit the transaction for processing and clearance by LCH.Clearnet. Bclear accepts only completed transactions and is not a matching system for counterparties.

¹⁸ LCH.Clearnet publishes its rules and procedures for the various markets cleared, together with information on risk management, application costs and procedures, minimum contributions towards and interest rates on the default fund, and transactions tariffs.

¹⁹ LCH.Clearnet has been approved as a Derivatives Clearing Organization (“DCO”) by the CFTC. In addition, FSA and the Bank of England performed a risk assessment of LCH in June 2006 against the *Recommendations for Central Counterparties* (“RCCP”), which was drafted by a joint task force composed of representative members of the International Organization of Securities Commissions (“IOSCO”) and Committee on Payment and Settlement Systems (“CPSS”) and published in November 2004.

The Task Force consisted of securities regulators and central bankers from 19 countries and the European Union. The U.S. representatives on the Task Force included staff from the Commission, FRB, and the CFTC. The complete RCCP Report is available on the Web sites of the Bank for International Settlements and the International Organization of Securities Commission at, <http://www.bis.org/publ/cpss64.htm>, and at <http://www.iosco.org>, respectively. LCH.Clearnet has

assured the Commission that it is in full compliance with the *Recommendations for Central Counterparties*. The assessment can be found at <http://www.fsa.gov.uk/pubs/other/lchclearnet.pdf>.

²⁰ LCH.Clearnet is owned 73.3 percent by users, 10.9 percent by exchanges, and 15.8 percent by Euroclear. Euroclear is a user-owned, user-governed Brussels, Belgium-based financial services company that specializes in the settlement of securities transactions.

²¹ An “exchange contract” refers to a contract that is subject to the rules of LIFFE A&M. The term does not indicate that a central order book exists for a product.

clearing member on each side of the transaction.

Through this process, the index CDS is discharged and a set of on-exchange contracts arise imposing equivalent obligations on and granting equivalent rights to the original parties to the index CDS, but with LCH.Clearnet as the CCP. Because the non-member customer will not be a party to a contract registered with LCH.Clearnet by the clearing member, the relationship between the non-member customer and the non-clearing member will remain intact, although such relationship will now be based upon the exchange contract, rather than the index CDS originally entered into by the respective parties.

3. LCH Risk Management

LCH.Clearnet requires the posting of initial margin and maintenance ("variation") margin for all clearing accounts. The initial margin and maintenance margin is determined utilizing the London SPAN (Standard Portfolio Analysis of Risk) methodology. London SPAN was adapted from the Chicago Mercantile Exchange's margining system.

The initial margin requirement for a member's CDS portfolio is the largest loss identified under these various market conditions that might reasonably occur taking into account risk offsets within the CDS portfolio. Initial margin is refunded when the margined index CDS position is closed. This risk management methodology is designed to protect LCH.Clearnet against the worst likely loss from one or two days' move in the market.

Net Liquidation Value ("NLV"), the value of a member's portfolio at closing market prices representing the income or expenditure which would be associated with closing out an index CDS position, is added to initial margin to give the total margin requirement.

LCH.Clearnet revalues the margin positions of its members on at least a daily basis to account for changes or volatility in the market price of the underlying index and in LCH.Clearnet's valuation of margin collateral provided in the form of securities. During the day, LCH.Clearnet monitors market prices and clearing members' positions and may call for additional margin payments from members. LCH.Clearnet then revalues each member's margin requirements each night.²²

²² While LCH.Clearnet's margin requirements are central to its risk management, LCH.Clearnet also has other measures at its disposal, including:

1. Additional financial resource requirements (buffers);
2. Additional initial margin requirements;
3. Imposition of position limits;

LCH.Clearnet's margin requirements are only applicable to clearing members. All clearing members must provide LCH.Clearnet with enough margin to cover the risk on their total net positions for each account they clear. Clearing members and/or non-clearing members in turn set the margin requirements applicable to their customers.

4. Margin Collateral

LCH.Clearnet accepts a wide variety of collateral types from clearing members in meeting their initial and NLV margin payments. Members may meet their margin requirements by cash payments in the following currencies: sterling, U.S. dollars, yen, Swiss francs, and euros. In addition, LCH.Clearnet will accept an extensive range of collateral including approved bank guarantees, certain U.K. treasury bills, U.K. gilts, sterling, U.S. dollar certificates of deposit, German, Italian, and Spanish government bonds and U.K. equities.

To avoid frequent margin payments, clearing members may deposit margin in excess of the LCH.Clearnet required minimum. In such cases, LCH.Clearnet pays interest to clearing members on excess cash margin on deposit currently at the overnight London Inter-Bank Bid Rate ("LIBID") minus twenty-five basis points.

5. Member Default

If a clearing member appears to LCH.Clearnet to be unable, or likely to become unable, to meet its obligations to LCH.Clearnet, it may be declared by LCH.Clearnet in default under LCH.Clearnet's default rules in relation to the contracts registered by it with LCH.Clearnet. Where a clearing member has been declared in default by LCH.Clearnet, contracts between such clearing member and its non-clearing members and clients will be dealt with under LIFFE A&M's default rules. A default by a non-clearing member will also be dealt with under LIFFE A&M's default rules. Where the defaulting party is an LCH.Clearnet clearing member, LCH.Clearnet's default rules take primacy over LIFFE A&M's, although all actions in such circumstances are typically coordinated between LCH.Clearnet and LIFFE A&M to take

4. Trading for liquidation only;
5. Prior authorization of trades above a certain size; and
6. Issuing instructions to reduce positions.

LCH.Clearnet also monitors large cumulative profits or losses. If large and unusual trading activity is detected (relative to previous exposures), LCH.Clearnet will contact compliance officers and seek assurances from the senior executives or boards of a member firm or parent company.

advantage of statutory protections afforded to LCH.Clearnet as an RCH.

As the legal counterparty to each clearing member, LCH.Clearnet bears any loss arising from the default of a clearing member, beyond the margin deposits held as security in respect of the defaulting member's liabilities. LCH.Clearnet's supplementary resources for use in default cases, should a member's margin deposits prove insufficient, comprise a Default Fund, totaling approximately 600 million, which is provided by members and held in cash by LCH. Each member's Default Fund contribution is assessed every three months on the basis of that member's initial margin and (in the case of exchange traded derivatives) trading volumes over the preceding three months.

The Default Fund is "mutualized" in that any loss faced by LCH.Clearnet as a result of a default which cannot be met from the defaulter's margin on deposit at LCH.Clearnet or from its contribution to the Default Fund will be met by the Default Fund generally. Customers of a defaulting clearing member have no contractual relationship with LCH.Clearnet, but are protected to the extent of their client agreement with the defaulting member and any segregation arrangements in place with the defaulting member.²³

LCH.Clearnet uses a stress testing model to ensure that its post-default financial backing is sufficient. The stress testing model assesses the adequacy of initial margin requirements and the Default Fund on the basis of extreme price movement scenarios in all contracts cleared by LCH.

The sequence of protections to be applied in the event of a default is as follows:²⁴

- a. Defaulting Member's Initial Margin (including excess collateral posted).
- b. Defaulting Member's Default Fund Contribution.
- c. Up to £20 million of LCH.Clearnet's capital and reserves.
- d. Remainder of the Default Fund.
- e. Remainder of LCH.Clearnet's capital and reserves.

As the counterparty to every clearing member, LCH.Clearnet reduces the scope of counterparty risk between clearing members. LCH.Clearnet is legally responsible for the financial performance of the contracts that it has registered and any resulting delivery obligations. LCH.Clearnet represents

²³ LCH is not a counterparty to contracts that clearing members have with their customers.

²⁴ The sequence does not take into account the anticipated replenishment of the Default Fund by market members and/or national governments between steps d. and e.

that its rules and procedures are available on its Web site and such rules and procedures generally set forth the sequence of protections to be applied in the event of a default by a clearing member.

6. Client Money Rules and Other Member Requirements

Clearing members that undertake business for clients are subject to UK client money and client asset rules or, if they are authorized outside the UK, similar rules of their relevant regulator. In the European Union, the client money rules are governed by the Markets in Financial Instruments Directive, although the UK client money rules prescribe some extended conditions in certain cases. Clearing members may have two accounts with LCH.Clearnet, one for segregated customer business and one for all house and non-segregated client business, and neither LCH.Clearnet nor the clearing member can offset liabilities on the house margin account with credits arising on the client margin account. Clearing members are required to segregate customer funds and securities except in instances where the investor, if permitted to do so, contracts out of the segregation requirement.

LIFFE A&M represents that it only considers for membership entities located in jurisdictions with regulatory arrangements it deems satisfactory regarding: (i) Supervision of investment activity; (ii) information sharing and cooperation between the supervisory authority of the jurisdiction concerned and LIFFE A&M and/or the FSA; and (iii) capital adequacy, liquidity, and segregation of customers' funds and securities (and related books and records provisions). LIFFE A&M further represents that before offering Index CDS services to U.S. persons, LIFFE A&M will adopt a requirement that will prohibit a member from directly or indirectly submitting, or permitting an authorized customer to submit, an Index CDS to the Bclear service when the member receives or holds funds or securities of U.S. persons for the purpose of purchasing, selling, clearing, settling, or holding that Index CDS position, unless the member, in connection with such Index CDS activities, is regulated by: (i) a signatory to the IOSCO Multilateral Memorandum of Understanding Concerning Consultation and Cooperation and the Exchange of Information, (ii) a signatory to a bilateral arrangement with the Commission for enforcement cooperation, or (iii) a financial regulatory authority in Ireland or Sweden. In that regard, LIFFE A&M

states that it intends to launch the Index CDS service for non-U.S. persons on December 22, 2008. LIFFE A&M will notify members at that time that the service may not be offered to U.S. persons until LIFFE A&M issues an additional notice.

In addition, LCH.Clearnet represents that its rules require its clearing members to: (i) Meet specific capital adequacy standards that vary depending on the type of activities undertaken by the member; (ii) provide copies of audited annual financial statements to LCH.Clearnet; and (iii) notify LCH.Clearnet upon the happening of certain material events, such as significant reductions in shareholders' funds or net capital.

B. Temporary Conditional Exemption From Clearing Agency Registration Requirement

Section 17A of the Exchange Act sets forth the framework for the regulation and operation of the U.S. clearance and settlement system, including CCPs. Specifically, Section 17A directs the Commission to use its authority to promote enumerated Congressional objectives and to facilitate the development of a national clearance and settlement system for securities transactions. Absent an exemption, a CCP that novates trades of non-excluded CDS that are securities and generates money and settlement obligations for participants is required to register with the Commission as a clearing agency.

Section 36 of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of the Exchange Act or any rule or regulation thereunder, by rule, regulation, or order, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.²⁵

Accordingly, pursuant to section 36 of the Exchange Act, the Commission finds that it is necessary or appropriate in the public interest and is consistent with the protection of investors to exercise its authority to grant an exemption until September 25, 2009 to LCH.Clearnet from section 17A of the Exchange Act, solely to perform the functions of a clearing agency for Cleared Index CDS,²⁶ subject to the conditions discussed below.

²⁵ 15 U.S.C. 78mm.

²⁶ For purposes of this exemption, and the other exemptions addressed in this Order, "Cleared Index CDS" means a credit default swap that is submitted

Our action today balances the aim of facilitating the prompt establishment of LCH.Clearnet as a CCP for non-excluded CDS transactions—which should help reduce systemic risks during a period of extreme turmoil in the U.S. and global financial markets—with ensuring that important elements of Commission oversight are applied to the non-excluded CDS market. In doing so, we are mindful that applying the full scope of the Exchange Act to transactions involving non-excluded CDS could deter the prompt establishment of LCH.Clearnet as a CCP to settle those transactions.

While we are acting so that the prompt establishment of LCH.Clearnet as a CCP for non-excluded CDS will not be delayed by the need to apply the full scope of Exchange Act section 17A's requirements that govern clearing agencies, the relief we are providing is temporary and conditional. The limited duration of the exemptions will permit the Commission to gain more direct experience with the non-excluded CDS market after LCH.Clearnet becomes operational, giving the Commission the ability to oversee the development of the centrally cleared non-excluded CDS market as it evolves. During the exemptive period, the Commission will closely monitor the impact of the CCPs on the CDS market. In particular, the Commission will seek to assure itself that the CCPs do not act in an anticompetitive manner or indirectly facilitate anticompetitive behavior with respect to fees charged to members, the dissemination of market data and the access to clearing services by independent CDS exchanges or CDS trading platforms. The Commission will take that experience into account in future actions.

(or offered, purchased, or sold on terms providing for submission) to LCH.Clearnet, that is offered only to, purchased only by, and sold only to eligible contract participants (as defined in Section 1a(12) of the Commodity Exchange Act as in effect on the date of this Order (other than a person that is an eligible contract participant under paragraph (C) of that section)), and in which the reference index is an index in which 80 percent or more of the index's weighting is comprised of the following entities or securities: (i) An entity reporting under the Exchange Act, providing Securities Act Rule 144A(d)(4) information, or about which financial information is otherwise publicly available; (ii) a foreign private issuer whose securities are listed outside the United States and that has its principal trading market outside the United States; (iii) a foreign sovereign debt security; (iv) an asset-backed security, as defined in Regulation AB, issued in a registered transaction with publicly available distribution reports; or (v) an asset-backed security issued or guaranteed by the Fannie Mae, Freddie Mac, or the Government National Mortgage Association ("Ginnie Mae"). As discussed above, the Commission's action today does not affect CDS that are swap agreements under Section 206A of the Gramm-Leach-Bliley Act. See text at note 10, *supra*.

Moreover, this temporary exemption in part is based on LCH.Clearnet's representation that it meets the standards set forth in the RCCP.²⁷ The RCCP establishes a framework that requires a CCP to have: (i) The ability to facilitate the prompt and accurate clearance and settlement of CDS transactions and to safeguard its users' assets; and (ii) sound risk management, including the ability to appropriately determine and collect clearing fund and monitor its users' trading. This framework is generally consistent with the requirements of section 17A of the Exchange Act.

In addition, this Order is designed to assure that—as LCH.Clearnet and LIFFE A&M have represented—information will be available to market participants about the terms of the CDS cleared by LCH.Clearnet, the creditworthiness of LCH.Clearnet or any guarantor, and the clearing and settlement process for the CDS. Moreover, to be within the definition of Cleared Index CDS for purposes of this exemption (as well as the other exemptions granted through this Order), at least 80 percent of the weighting of the index must be comprised of reference entities or reference securities that satisfy certain conditions relating to the availability of information about such persons or securities. The definition does not prescribe the type of financial information that must be available nor the location of the particular information, recognizing that eligible contract participants have access to information about reference entities and reference securities through multiple sources. The Commission believes, however, that it is important in the CDS market, as in the market for securities generally, that parties to transactions should have access to financial information that would allow them to appropriately evaluate the risks relating to a particular investment and make more informed investment decisions.²⁸ Such information availability also will assist LCH.Clearnet and the buyers and sellers in valuing their Cleared Index CDS and their counterparty exposures. As a result of the Commission's actions today, the Commission believes that information should be available for market participants to be able to make

informed investment decisions, and value and evaluate their Cleared Index CDS and their counterparty exposures.

This temporary exemption is subject to a number of conditions that are designed to enable Commission staff to monitor LCH.Clearnet's clearance and settlement of CDS transactions, coordinate and cooperate with the FSA, and help reduce risk in the CDS market. These conditions require that LCH.Clearnet: (i) Make available on its Web site annual audited financial statements; (ii) preserve records related to the conduct of its Cleared Index CDS clearance and settlement services for at least five years (in an easily accessible place for the first two years); (iii) supply information relating to its Cleared Index CDS clearance and settlement services to the Commission; (iv) provide access to the Commission to conduct on-site inspections of facilities, records and personnel related to its Cleared Index CDS clearance and settlement services, subject to coordination with FSA and upon terms and conditions agreed between the FSA and the Commission; (v) notify the Commission about material disciplinary actions taken against users of its Cleared Index CDS clearance and settlement services, and about the involuntary termination of the membership of an entity using those services; (vi) provide the Commission with prior notice of changes to its Default Rules and Default Fund Rules; (vii) provide the Commission with reports with respect to certain automated systems used in connection with its Cleared Index CDS clearance and settlement services, and with annual audited financial statements;²⁹ and (viii) provide notice to the Commission regarding the suspension of services or the inability to operate facilities in connection with its Cleared Index CDS clearance and settlement services.

In addition, this relief is conditioned on LCH.Clearnet, directly or indirectly, making available to the public on terms that are fair and reasonable and not unreasonably discriminatory: (i) All end-of-day settlement prices and any other prices with respect to Cleared

Index CDS that LCH.Clearnet may establish to calculate mark-to-market margin requirements for LCH.Clearnet or LIFFE A&M participants; and (ii) any other pricing or valuation information with respect to Cleared Index CDS as is published or distributed by LCH.Clearnet or LIFFE A&M. The Commission believes this is an appropriate condition for LCH.Clearnet's exemption from registration as a clearing agency. In section 11A of the Exchange Act, Congress included a finding that “[i]t is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure * * * the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.”³⁰ The President's Working Group on Financial Markets has stated that increased transparency is a policy objective for the over-the-counter derivatives market,³¹ which includes the market for CDS. This condition is designed to further this policy objective of both Congress and the President's Working Group by requiring LCH.Clearnet and LIFFE A&M to make available to the public on terms that are fair and reasonable all end-of-day settlement prices and any other prices with respect to Cleared Index CDS that LCH.Clearnet may establish to calculate mark-to-market margin requirements for LCH.Clearnet or LIFFE A&M Participants. In addition, LCH.Clearnet or LIFFE A&M must make available to the public on terms that are fair and reasonable and not unfairly discriminatory any other pricing or valuation information with respect to Cleared Index CDS as is published or distributed by LCH.Clearnet or LIFFE A&M.

As a CCP, LCH.Clearnet will collect and process information about CDS transactions and positions from all of its participants. With this information, a CCP will, among other things, calculate and disseminate current values for open positions for the purpose of setting appropriate margin levels, or have an agent perform these functions on its behalf. The availability of such information can improve fairness, efficiency, and competitiveness of the

²⁷ See note 19, *supra*.

²⁸ The Commission notes the recommendations of the President's Working Group on Financial Markets regarding the informational needs and due diligence responsibilities of investors. See Policy Statement on Financial Market Developments, The President's Working Group on Financial Markets, March 13, 2008, available at: http://www.treas.gov/press/releases/reports/pwgpolicystatementkturmoil_03122008.pdf.

²⁹ As a condition of LCH.Clearnet's exemption, LIFFE A&M has agreed to provide the Commission with reports with respect to certain automated systems used in connection with LCH.Clearnet's Cleared Index CDS clearance and settlement services. These reports will be generated in accordance with risk assessments of the areas set forth in the Commission's Automation Review Policy Statements (“ARPs”). See Automated Systems of Self-Regulatory Organization, Securities Exchange Act Release No. 27445 (November 16, 1989), 54 FR 48703 (November 24, 1989), and Automated Systems of Self-Regulatory Organization (II), Securities Exchange Act Release No. 29185 (May 9, 1991), 56 FR 22490 (May 15, 1991).

³⁰ 15 U.S.C. 78k-1(a)(1)(C)(iii). See also 15 U.S.C. 78k-1(a)(1)(D).

³¹ See President's Working Group on Financial Markets, Policy Objectives for the OTC Derivatives Market (November 14, 2008), <http://www.ustreas.gov/press/releases/reports/policyobjectives.pdf> (“Public reporting of prices, trading volumes and aggregate open interest should be required to increase market transparency for participants and the public.”).

market—all of which enhance investor protection and facilitate capital formation. Moreover, with pricing and valuation information relating to Cleared Index CDS, market participants would be able to derive information about underlying securities and indexes. This may improve the efficiency and effectiveness of the securities markets by allowing investors to better understand credit conditions generally.

C. Temporary General Exemption for LCH.Clearnet, LIFFE A&M and Certain Eligible Contract Participants

Applying the full panoply of Exchange Act requirements to participants in transactions in non-excluded CDS likely would deter some participants from using CCPs to clear CDS transactions. At the same time, it is important that the antifraud provisions of the Exchange Act apply to transactions in non-excluded CDS; indeed, OTC transactions subject to individual negotiation that qualify as security-based swap agreements already are subject to these antifraud provisions.³²

We thus believe that it is appropriate in the public interest and consistent with the protection of investors temporarily to apply substantially the same framework to transactions by market participants in non-excluded CDS that applies to transactions in security-based swap agreements. Applying substantially the same set of requirements to participants in transactions in non-excluded CDS as apply to participants in OTC CDS transactions will avoid deterring market participants from promptly using CCPs,

³² While Section 3A of the Exchange Act excludes “swap agreements” from the definition of “security,” certain antifraud and insider trading provisions under the Exchange Act explicitly apply to security-based swap agreements. See (a) paragraphs (2) through (5) of Section 9(a), 15 U.S.C. 78i(a), prohibiting the manipulation of security prices; (b) Section 10(b), 15 U.S.C. 78j(b), and underlying rules prohibiting fraud, manipulation or insider trading (but not prophylactic reporting or recordkeeping requirements); (c) Section 15(c)(1), 15 U.S.C. 78o(c)(1), which prohibits brokers and dealers from using manipulative or deceptive devices; (d) Sections 16(a) and (b), 15 U.S.C. 78p(a) and (b), which address disclosure by directors, officers and principal stockholders, and short-swing trading by those persons, and rules with respect to reporting requirements under Section 16(a); (e) Section 20(d), 15 U.S.C. 78t(d), providing for antifraud liability in connection with certain derivative transactions; and (f) Section 21A(a)(1), 15 U.S.C. 78u-1(a)(1), related to the Commission’s authority to impose civil penalties for insider trading violations.

“Security-based swap agreement” is defined in Section 206B of the Gramm-Leach-Bliley Act as a swap agreement in which a material term is based on the price, yield, value, or volatility of any security or any group or index of securities, or any interest therein.

which would detract from the potential benefits of central clearing.

Accordingly, pursuant to section 36 of the Exchange Act, the Commission finds that it is necessary or appropriate in the public interest and is consistent with the protection of investors to exercise its authority to grant an exemption until September 25, 2009 from certain requirements under the Exchange Act. This temporary exemption applies to LCH.Clearnet and LIFFE A&M, and also to certain eligible contract participants³³ other than: Eligible contract participants that receive or hold funds or securities for the purpose of purchasing, selling, clearing, settling or holding Cleared Index CDS positions for other persons;³⁴ eligible contract participants that are self-regulatory organizations; or eligible contract participants that are registered brokers or dealers.³⁵

Under this temporary exemption, and solely with respect to Cleared Index CDS, these persons generally are exempt from provisions of the Exchange Act and the rules and regulations thereunder that do not apply to security-based swap agreements. Those persons thus would still be subject to those Exchange Act requirements that explicitly are applicable in connection with security-based swap agreements.³⁶ In addition, all provisions of the Exchange Act related to the Commission’s enforcement authority in connection with violations or potential violations of such provisions would remain applicable.³⁷ In this way, the temporary exemption would apply the

³³ This exemption in general applies to eligible contract participants, as defined in Section 1a(12) of the Commodity Exchange Act as in effect on the date of this Order, other than persons that are eligible contract participants under paragraph (C) of that section.

³⁴ For these purposes, and for the purpose of the definition of “Cleared Index CDS,” the terms “purchasing” and “selling” mean the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing the rights or obligations under, a Cleared Index CDS, as the context may require. This is consistent with the meaning of the terms “purchase” or “sale” under the Exchange Act in the context of security-based swap agreements. See Exchange Act Section 3A(b)(4).

A separate temporary conditional exemption addresses members of LIFFE A&M that hold funds or securities for the purpose of purchasing, selling, clearing, settling, or holding Cleared Index CDS positions for other persons. See Part II.D, *infra*.

³⁵ A separate temporary exemption addresses the Cleared Index CDS activities of registered broker-dealers. See Part II.E, *infra*.

³⁶ See note 32, *supra*.

³⁷ Thus, for example, the Commission retains the ability to investigate potential violations and bring enforcement actions in the federal courts and administrative proceedings, and to seek the full panoply of remedies available in such cases.

same Exchange Act requirements in connection with non-excluded CDS as apply in connection with OTC credit default swaps.

This temporary exemption, however, does not extend to sections 5 and 6 of the Exchange Act. The Commission separately is issuing a conditional exemption from these provisions to all broker-dealers and exchanges.³⁸ This temporary exemption also does not extend to section 17A of the Exchange Act; instead, LCH.Clearnet is exempt from registration as a clearing agency under the conditions discussed above. In addition, this exemption does not apply to Exchange Act sections 12, 13, 14, 15(d) and 16;³⁹ eligible contract participants and other persons instead should refer to the interim final temporary rules issued today by the Commission. Finally, this temporary exemption does not extend to the Commission’s administrative proceeding authority under sections 15(b)(4) and (b)(6),⁴⁰ or to certain provisions related to government securities.⁴¹

³⁸ See note 16, *supra*. A national securities exchange that effects transactions in Cleared Index CDS would continue to be required to comply with all requirements under the Exchange Act applicable to such transactions. A national securities exchange could form subsidiaries or affiliates that operate exchanges exempt under that order. Any subsidiary or affiliate of a registered exchange could not integrate, or otherwise link, the exempt CDS exchange with the registered exchange including the premises or property of such exchange for effecting or reporting a transaction without being considered a “facility of the exchange.” See Section 3(a)(2), 15 U.S.C. 78c(a)(2).

³⁹ 15 U.S.C. 78l, 78m, 78n, 78o(d), 78p.

⁴⁰ Exchange Act Sections 15(b)(4) and 15(b)(6), 15 U.S.C. 78o(b)(4) and (b)(6), grant the Commission authority to take action against broker-dealers and associated persons in certain situations. Accordingly, while this exemption generally extends to persons that act as inter-dealer brokers in the market for Cleared Index CDS and do not hold funds or securities for others, such inter-dealer brokers may be subject to actions under Sections 15(b)(4) and (b)(6) of the Exchange Act.

In addition, such inter-dealer brokers may be subject to actions under Exchange Act Section 15(c)(1), 15 U.S.C. 78o(c)(1), which prohibits brokers and dealers from using manipulative or deceptive devices. As noted above, Section 15(c)(1) explicitly applies to security-based swap agreements. Sections 15(b)(4), 15(b)(6) and 15(c)(1), of course, would not apply to persons subject to this exemption who do not act as broker-dealers or associated persons of broker-dealers.

⁴¹ This exemption specifically does not extend to the Exchange Act provisions applicable to government securities, as set forth in Section 15C, 15 U.S.C. 78o-5, and its underlying rules and regulations; nor does the exemption extend to related definitions found at paragraphs (42) through (45) of Section 3(a), 15 U.S.C. 78c(a). The Commission does not have authority under Section 36 to issue exemptions in connection with those provisions. See Exchange Act Section 36(b), 15 U.S.C. 78mm(b).

D. Conditional Temporary General Exemption for Certain Clearing Members of LIFFE A&M and LCH.Clearnet

Absent an exception, persons that effect transactions in non-excluded CDS that are securities may be required to register as broker-dealers pursuant to section 15(a)(1) of the Exchange Act.⁴² Moreover, certain reporting and other requirements of the Exchange Act could apply to such persons, as broker-dealers, regardless of whether they are registered with the Commission.

It is consistent with our investor protection mandate to require that intermediaries in securities transactions that receive or hold funds and securities on behalf of others comply with standards that safeguard the interests of their customers. For example, registered broker-dealers are required to segregate assets held on behalf of customers from proprietary assets, because segregation will assist customers in recovering assets in the event the intermediary fails. To the extent that funds and securities are not segregated, they could be used by a participant to fund its own business and could be attached to satisfy debts of the participant were the participant to fail. Moreover, the maintenance of adequate capital and liquidity protects customers, CCPs and other market participants. Adequate books and records (including both transactional and position records) are necessary to facilitate day to day operations as well as to help resolve situations in which a participant fails and either a regulatory authority or receiver is forced to liquidate the firm. Appropriate records also are necessary to allow examiners to review for improper activities, such as insider trading or fraud.

At the same time, requiring intermediaries that receive or hold

funds and securities on behalf of customers in connection with transactions in non-excluded CDS to register as broker-dealers may deter the use of CCPs in CDS transactions, to the detriment of the markets and market participants generally. Also, as noted above with regard to other eligible contract participants to non-excluded CDS transactions, immediately applying the panoply of Exchange Act requirements to centrally cleared transactions may deter the use of CCPs for CDS transactions.

Those factors argue in favor of flexibility in applying the requirements of the Exchange Act to these intermediaries. Along with those factors, in granting an exemption here we are particularly relying on the representation of LIFFE A&M that it only considers for membership entities located in jurisdictions with regulatory arrangements it deems satisfactory regarding: (i) Supervision of investment activity; (ii) information sharing and cooperation between the supervisory authority of the jurisdiction concerned and LIFFE A&M and/or the FSA; and (iii) capital adequacy, liquidity, and segregation of customers' funds and securities (and related books and records provisions). We also are particularly relying on the representation of LCH.Clearnet that its rules require its clearing members to: (i) Meet specific capital adequacy standards that vary depending on the type of activities undertaken by the member; (ii) provide copies of audited annual financial statements to LCH.Clearnet; and (iii) notify LCH.Clearnet upon the happening of certain material events, such as significant reductions in shareholders' funds or net capital.

We further are relying on LIFFE A&M's representation that before offering Index CDS services to U.S. persons,⁴³ LIFFE A&M will adopt a requirement that will prohibit a member from directly or indirectly submitting, or permitting an authorized customer to submit, an Index CDS to the Bclear service when the member receives or holds funds or securities of U.S. persons for the purpose of purchasing, selling, clearing, settling, or holding that Index CDS position, unless the member, in connection with such Index CDS activities, is regulated by: (i) A signatory to the IOSCO Multilateral Memorandum of Understanding Concerning

Consultation and Cooperation and the Exchange of Information, (ii) a signatory to a bilateral arrangement with the Commission for enforcement cooperation, or (iii) a financial regulatory authority in Ireland or Sweden.⁴⁴ This will help ensure that the Commission can access trading records and other information of LIFFE A&M members as needed to enforce the federal securities laws.

Accordingly, pursuant to section 36 of the Exchange Act, the Commission finds that it is necessary or appropriate in the public interest and is consistent with the protection of investors to exercise its authority to grant a conditional exemption until September 25, 2009 from certain Exchange Act requirements. In general, we are providing a temporary exemption, subject to the conditions discussed below, to any member of LIFFE A&M that receives or holds funds or securities for the purpose of purchasing, selling, clearing, settling or holding Cleared Index CDS positions for other persons. Solely with respect to Cleared Index CDS, those members generally will be exempt from those provisions of the Exchange Act and the underlying rules and regulations that do not apply to security-based swap agreements.⁴⁵

As with the exemption discussed above that is applicable to LCH.Clearnet, LIFFE A&M and certain eligible contract participants, and for the same reasons, this exemption for LIFFE A&M members that receive or hold funds and securities does not extend to Exchange Act provisions that explicitly apply in connection with security-based swap agreements,⁴⁶ or to related enforcement authority provisions.⁴⁷ As with the exemption discussed above, we also are not exempting those members from sections 5, 6, 12(a) and (g), 13, 14, 15(b)(4), 15(b)(6), 15(d), 16 and 17A of the Exchange Act.⁴⁸

This temporary exemption is subject to the member complying with conditions that are important for protecting customer funds and

⁴² 15 U.S.C. 78o(a)(1). This section generally provides that, absent an exception or exemption, a broker or dealer that uses the mails or any means of interstate commerce to effect transactions in, or to induce or attempt to induce the purchase or sale of, any security must register with the Commission.

Section 3(a)(4) of the Exchange Act generally defines a "broker" as "any person engaged in the business of effecting transactions in securities for the account of others," but provides 11 exceptions for certain bank securities activities. 15 U.S.C. 78c(a)(4). Section 3(a)(5) of the Exchange Act generally defines a "dealer" as "any person engaged in the business of buying and selling securities for his own account," but includes exceptions for certain bank activities. 15 U.S.C. 78c(a)(5). Exchange Act Section 3(a)(6) defines a "bank" as a bank or savings association that is directly supervised and examined by state or federal banking authorities (with certain additional requirements for banks and savings associations that are not chartered by a federal authority or a member of the Federal Reserve System). 15 U.S.C. 78c(a)(6).

⁴³ As noted above, LIFFE A&M states that it intends to launch the Index CDS service for non-U.S. persons on December 22, 2008. LIFFE A&M will notify members at that time that that the service may not be offered to U.S. persons until LIFFE A&M issues an additional notice.

⁴⁴ The Commission has established informal relationships with securities authorities in Ireland and Sweden and cooperates with them on an *ad hoc* basis. The Commission will explore entering into arrangements for cooperation with these authorities and, in the near term, will seek letters of intent to cooperate.

⁴⁵ This exemption will be available both to clearing members and to non-clearing members of LIFFE A&M that hold funds and securities on behalf of others in connection with transactions in Cleared Index CDS.

⁴⁶ See note 32, *supra*.

⁴⁷ See note 37, *supra*.

⁴⁸ Nor are we exempting those members from provisions related to government securities, as discussed above.

securities. Particularly, the member must be in material compliance with the rules of LIFFE A&M and, if it is a clearing member, with the rules of LCH.Clearnet, and applicable laws and regulations, relating to capital, liquidity, and segregation of customers' funds and securities (and related books and records provisions) with respect to non-excluded CDS.⁴⁹ Also, to the extent that the member receives or holds funds or securities of U.S. eligible contract participants for the purpose of purchasing, selling, clearing, settling or holding non-excluded CDS positions for those persons, this exemption is predicated on the member satisfying the following three conditions: (i) The U.S. persons cannot be natural persons; (ii) the member must segregate such funds and securities of such U.S. persons from the member's own assets (*i.e.*, the member may not permit U.S. persons to "opt out" of applicable segregation requirements for such funds and securities even if regulations or laws would permit the person to "opt out"); and (iii) the member shall disclose to such U.S. persons that the member is not regulated by the Commission and that U.S. broker-dealer segregation requirements and protections under the Securities Investor Protection Act will not apply to any funds or securities held by the member.

E. Temporary General Exemption for Certain Registered Broker-Dealers

The temporary exemptions addressed above—with regard (i) to LCH.Clearnet, LIFFE A&M and certain eligible contract participants and (ii) to LIFFE A&M members that receive or hold funds and securities of others—are not available to persons that are registered as broker-dealers with the Commission (other than those that are notice registered pursuant to section 15(b)(11)).⁵⁰ The Exchange Act and its underlying rules and regulations require broker-dealers to comply with a number of obligations that are important to protecting investors and promoting market integrity. We are mindful of the need to avoid creating disincentives to the prompt use of CCPs, and we recognize that the factors discussed above suggest that the full panoply of Exchange Act requirements should not immediately be applied to registered broker-dealers that

engage in transactions involving Cleared Index CDS. At the same time, we also are sensitive to the critical importance of certain broker-dealer requirements to promoting market integrity and protecting customers (including those broker-dealer customers that are not involved with CDS transactions).

This calls for balancing the facilitation of the development and prompt implementation of CCPs with the preservation of certain key investor protections. Pursuant to section 36 of the Exchange Act, the Commission finds that it is necessary or appropriate in the public interest and is consistent with the protection of investors to exercise its authority to grant an exemption until September 25, 2009 from certain Exchange Act requirements. Consistent with the temporary exemptions discussed above, and solely with respect to Cleared Index CDS, we are exempting registered broker-dealers in general from provisions of the Exchange Act and its underlying rules and regulations that do not apply to security-based swap agreements. As above, we are not excluding registered broker-dealers from Exchange Act provisions that explicitly apply in connection with security-based swap agreements or from related enforcement authority provisions.⁵¹ As above, and for similar reasons, we are not exempting registered broker-dealers from: Sections 5, 6, 12(a) and (g), 13, 14, 15(b)(4), 15(b)(6), 15(d), 16 and 17A of the Exchange Act.⁵²

Further we are not exempting registered broker-dealers from the following additional provisions under the Exchange Act: (1) Section 7(c),⁵³ which addresses the unlawful extension of credit by broker-dealers; (2) Section 15(c)(3),⁵⁴ which addresses the use of unlawful or manipulative devices by broker-dealers; (3) Section 17(a),⁵⁵ regarding broker-dealer obligations to make, keep and furnish information; (4) Section 17(b),⁵⁶ regarding broker-dealer records subject to examination; (5) Regulation T,⁵⁷ a Federal Reserve Board regulation regarding extension of credit by broker-dealers; (6) Exchange Act Rule 15c3-1, regarding broker-dealer net

capital; (7) Exchange Act Rule 15c3-3, regarding broker-dealer reserves and custody of securities; (8) Exchange Act Rules 17a-3 through 17a-5, regarding records to be made and preserved by broker-dealers and reports to be made by broker-dealers; and (9) Exchange Act Rule 17a-13, regarding quarterly security counts to be made by certain exchange members and broker-dealers. Registered broker-dealers should comply with these provisions in connection with their activities involving non-excluded CDS because these provisions are especially important to helping protect customer funds and securities, ensure proper credit practices and safeguard against fraud and abuse.⁵⁸

F. Solicitation of Comments

The Commission intends to monitor closely the development of the CDS market and intends to determine to what extent, if any, additional regulatory action may be necessary. For example, as circumstances warrant, certain conditions could be added, altered, or eliminated. Moreover, because these exemptions are temporary, the Commission will in the future consider whether they should be extended or allowed to expire. The Commission believes it would be prudent to solicit public comment on its action today, and on what action it should take with respect to the CDS market in the future. The Commission is soliciting public comment on all aspects of these exemptions, including:

1. Whether the length of this temporary exemption (until September 25, 2009) is appropriate. If not, what should the appropriate duration be?
2. Whether the conditions to these exemptions are appropriate. Why or why not? Should other conditions apply? Are any of the present conditions to the exemptions provided in this Order unnecessary? If so, please specify and explain why such conditions are not needed.
3. Whether LCH.Clearnet ultimately should be required to register as a clearing agency under the Exchange Act. Why or why not?
4. Whether LIFFE A&M members that receive or hold funds or securities for the purpose of purchasing, selling, clearing, settling or holding non-excluded CDS positions for other persons ultimately should be required to

⁴⁹ A member would not be "in material compliance" if it failed in any way to segregate customer funds and securities consistent with these rules, laws and regulations. In that circumstance, the member could not rely on this exemption.

⁵⁰ Exchange Act Section 15(b)(11) provides for notice registration of certain persons that effect transactions in security futures products. 15 U.S.C. 78o(b)(11).

⁵¹ See notes 32 and 37, *supra*. As noted above, broker-dealers also would be subject to Section 15(c)(1) of the Exchange Act, which prohibits brokers and dealers from using manipulative or deceptive devices, because that provision explicitly applies in connection with security-based swap agreements.

⁵² We also are not exempting those members from provisions related to government securities, as discussed above.

⁵³ 15 U.S.C. 78g(c).

⁵⁴ 15 U.S.C. 78o(c)(3).

⁵⁵ 15 U.S.C. 78q(a).

⁵⁶ 15 U.S.C. 78q(b).

⁵⁷ 12 CFR 220.1 *et seq.*

⁵⁸ Indeed, Congress directed the Commission to promulgate broker-dealer financial responsibility rules, including rules regarding custody, the use of customer securities and the use of customers' deposits or credit balances, and regarding establishment of minimum financial requirements.

register as broker-dealers. Why or why not?

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/other.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number S7-34-08 on the subject line; or
- Use the Federal eRulemaking Portal (<http://www.regulations.gov/>). Follow the instructions for submitting comments.

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 S7-34-08. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. We will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/other.shtml>). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

III. Conclusion

It is hereby ordered, pursuant to section 36(a) of the Exchange Act, that, until September 25, 2009:

(a) Exemption from section 17A of the Exchange Act.

LCH.Clearnet Ltd. ("LCH.Clearnet") shall be exempt from section 17A of the Exchange Act solely to perform the functions of a clearing agency for Cleared Index CDS (as defined in paragraph (e) of this Order), subject to the following conditions:

(1) LCH.Clearnet shall make available on its Web site annual audited financial statements.

(2) LCH.Clearnet shall keep and preserve at least one copy of all documents, including all correspondence, memoranda, papers, books, notices, accounts, and other such records as shall be made or received by it relating to its Cleared Index CDS clearance and settlement services. These records shall be kept for at least five

years and for the first two years shall be held in an easily accessible place.

(3) LCH.Clearnet shall supply such information and periodic reports relating to its Cleared Index CDS clearance and settlement services as may be reasonably requested by the Commission.

(4) Subject to coordination with the FSA and upon such terms and conditions as may be agreed between the FSA and the Commission, LCH.Clearnet shall provide access to the Commission to conduct on-site inspections of all facilities (including automated systems and systems environment), records, and personnel related to LCH.Clearnet's Cleared Index CDS clearance and settlement services.

(5) LCH.Clearnet shall notify the Commission, on a monthly basis, of any material disciplinary actions taken against any of its members utilizing its Cleared Index CDS clearance and settlement services, including the denial of services, fines, or penalties. LCH.Clearnet shall notify the Commission promptly when it involuntarily terminates the membership of an entity that is utilizing LCH.Clearnet's Cleared Index CDS clearance and settlement services. Both notifications shall describe the facts and circumstances that led to LCH.Clearnet's disciplinary action.

(6) LCH.Clearnet shall provide the Commission with notice of all changes to its Default Rules and Default Fund Rules, not less than one day prior to effectiveness or implementation of such rule changes or, in exigent circumstances, as promptly as reasonably practicable under the circumstances. If LCH.Clearnet gives notice to, or seeks approval from, the FSA regarding any other changes to its rules regarding its Index CDS clearance and settlement services, LCH.Clearnet will also provide notice to the Commission. All such rule changes will be posted on LCH.Clearnet's Web site. Such notifications will not be deemed rule filings that require Commission approval.

(7) LCH.Clearnet shall provide the Commission with reports with respect to automated systems used in connection with Cleared Index CDS clearance and settlement services, other than the TRS/CPS system, prepared by independent audit personnel that are generated in accordance with risk assessment of the areas set forth in the Commission's Automation Review Policy Statements ("ARPs"). LIFFE A&M shall provide the Commission with reports with respect to its TRS/CPS system prepared by audit personnel from Risk and Audit Services, an

independent department of NYSE Euronext, that are generated in accordance with risk assessment of the areas set forth in the ARPs. LCH.Clearnet shall provide the Commission with annual audited financial statements prepared by independent audit personnel.

(8) LCH.Clearnet shall provide notice to the Commission at the same time it provides notice to the FSA in accordance with FSA REC 3.15 and FSA REC 3.16 regarding the suspension of services or inability to operate its facilities in connection with the clearance and settlement of Cleared Index CDS.

(9) LCH.Clearnet, directly or indirectly, shall make available to the public on terms that are fair and reasonable and not unreasonably discriminatory: (a) All end-of-day settlement prices and any other prices with respect to Cleared Index CDS that LCH.Clearnet or LIFFE A&M may establish to calculate mark-to-market margin requirements for LCH.Clearnet or LIFFE A&M Participants; and (b) any other pricing or valuation information with respect to Cleared Index CDS as is published or distributed by LCH.Clearnet or LIFFE A&M.

(b) Exemption for LCH.Clearnet, LIFFE A&M, and certain eligible contract participants.

(1) Persons eligible. The exemption in paragraph (b)(2) is available to:

- (i) LCH.Clearnet;
- (ii) LIFFE A&M;
- (iii) Any eligible contract participant (as defined in section 1a(12) of the Commodity Exchange Act as in effect on the date of this Order (other than a person that is an eligible contract participant under paragraph (C) of that section)), other than: (A) An eligible contract participant that receives or holds funds or securities for the purpose of purchasing, selling, clearing, settling, or holding Cleared Index CDS positions for other persons; (B) an eligible contract participant that is a self-regulatory organization, as that term is defined in Section 3(a)(26) of the Exchange Act; or (C) a broker or dealer registered under Section 15(b) of the Exchange Act (other than paragraph (11) thereof).

(2) Scope of exemption.

(i) In general. Such persons generally shall, solely with respect to Cleared Index CDS, be exempt from the provisions of the Exchange Act and the rules and regulations thereunder that do not apply in connection with security-based swap agreements. Accordingly, under this exemption, those persons would remain subject to those Exchange Act requirements that explicitly are

applicable in connection with security-based swap agreements (*i.e.*, paragraphs (2) through (5) of Section 9(a), Section 10(b), Section 15(c)(1), paragraphs (a) and (b) of Section 16, Section 20(d) and Section 21A(a)(1) and the rules thereunder that explicitly are applicable to security-based swap agreements). All provisions of the Exchange Act related to the Commission's enforcement authority in connection with violations or potential violations of such provisions also remain applicable.

(ii) Exclusions from exemption. The exemption in paragraph (b)(2)(i), however, does not extend to the following provisions under the Exchange Act:

(A) Paragraphs (42), (43), (44), and (45) of Section 3(a);

(B) Section 5;

(C) Section 6;

(D) Section 12 and the rules and regulations thereunder;

(E) Section 13 and the rules and regulations thereunder;

(F) Section 14 and the rules and regulations thereunder;

(G) Paragraphs (4) and (6) of Section 15(b);

(H) Section 15(d) and the rules and regulations thereunder;

(I) Section 15C and the rules and regulations thereunder;

(J) Section 16 and the rules and regulations thereunder; and

(K) Section 17A (other than as provided in paragraph (a)).

(c) Exemption for certain LIFFE A&M members.

Any member of LIFFE A&M that receives or holds funds or securities for the purpose of purchasing, selling, clearing, settling or holding Cleared Index CDS positions for other persons shall be exempt from the provisions of the Exchange Act and the rules and regulations thereunder specified in paragraph (b)(2), solely with respect to Cleared Index CDS, subject to the following conditions:

(1) The member shall be in material compliance with the rules of LIFFE A&M and, if a clearing member, with the rules of LCH.Clearnet, and applicable laws and regulations, relating to capital, liquidity, and segregation of customers' funds and securities (and related books and records provisions) with respect to Cleared Index CDS; and

(2) To the extent that the member receives or holds funds or securities of U.S. persons for the purpose of purchasing, selling, clearing, settling, or holding Cleared Index CDS positions:

(i) The U.S. persons shall not be natural persons;

(ii) The member shall segregate such funds and securities of such U.S.

persons from the member's own assets (*i.e.*, the member may not permit U.S. persons to "opt out" of applicable segregation requirements for such funds and securities even if regulations or laws would permit the person to "opt out"); and

(iii) The member shall disclose to such U.S. persons that the member is not regulated by the Commission and that U.S. broker-dealer segregation requirements and protections under the Securities Investor Protection Act will not apply to any funds or securities held by the member.

(d) Exemption for certain registered broker-dealers.

A broker or dealer registered under section 15(b) of the Exchange Act (other than paragraph (11) thereof) shall be exempt from the provisions of the Exchange Act and the rules and regulations thereunder specified in paragraph (b)(2), solely with respect to Cleared Index CDS, except:

(1) Section 7(c);

(2) Section 15(c)(3);

(3) Section 17(a);

(4) Section 17(b);

(5) Regulation T, 12 CFR 200.1 *et seq.*;

(6) Rule 15c3-1;

(7) Rule 15c3-3;

(8) Rule 17a-3;

(9) Rule 17a-4;

(10) Rule 17a-5; and

(11) Rule 17a-13.

(e) For purposes of this Order, "Cleared Index CDS" shall mean a credit default swap that is submitted (or offered, purchased or sold on terms providing for submission) to LCH.Clearnet, that is offered only to, purchased only by, and sold only to eligible contract participants (as defined in section 1a(12) of the Commodity Exchange Act as in effect on the date of this Order (other than a person that is an eligible contract participant under paragraph (C) of that section)), and in which the reference index is an index in which 80 percent or more of the index's weighting is comprised of the entities or securities described below:

(1) An entity reporting under the Exchange Act, providing Securities Act Rule 144A(d)(4) information, or about which financial information is otherwise publicly available;

(2) A foreign private issuer whose securities are listed outside the United States and that has its principal trading market outside the United States;

(3) A foreign sovereign debt security;

(4) An asset-backed security, as defined in Regulation AB, issued in a registered transaction with publicly available distribution reports; or

(5) An asset-backed security issued or guaranteed by Fannie Mae, Freddie Mac or Ginnie Mae.

By the Commission.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31193 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59152; File No. SR-CBOE-2008-127]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposal To Eliminate \$3 Underlying Price Requirement for Continued Listing and Listing of Additional Series

December 23, 2008.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on December 18, 2008, the Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 5.4.01 to eliminate the \$3 market price per share requirement from the Exchange's requirements for continued approval for an underlying security. The Exchange also proposes to amend Rule 5.4.02 by eliminating the prohibition against listing additional series of options on an underlying security at any time when the price per share of such underlying security is less than \$3. The text of the rule proposal is available on the Exchange's Web site (<http://www.cboe.org/legal>), at the Exchange's Office of the Secretary and at the Commission's Public Reference Room.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

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 IV 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to eliminate the \$3 market price per share requirement from the Exchange's requirements for continued approval for an underlying security from Rule 5.4.01(d). In addition, the rule filing would amend Rule 5.4.02 by eliminating the prohibition against listing additional series of options on an underlying security at any time when the price per share of such underlying security is less than \$3. Also, the Exchange proposes to make technical changes throughout the Interpretations and Policies to Rule 5.4 to eliminate references to paragraph (d) of Interpretation and Policy .01 to Rule 5.4.

The Exchange believes that the \$3 market price per share requirement is no longer necessary or appropriate, and states that only those underlying securities meeting the remaining maintenance listing criteria set forth in Rule 5.4.01 will be eligible for continued listing and the listing of additional option series. The Exchange believes that the current \$3 market price per share requirement could have a negative effect on investors. For example, in the current volatile market environment, the Exchange is currently unable to list new series on underlying securities trading below \$3. If there is market demand for series below \$3, the Exchange would be unable to accommodate such requests and investors would be unable to hedge their positions with options series with strikes below \$3.

2. Statutory Basis

Because the current rule proposal will permit the Exchange to make options on underlying securities available even if the price of the underlying security is less than \$3, the Exchange believes the

rule proposal is consistent with the Act and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act.⁴ Specifically, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) Act⁵ requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition 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 neither solicited nor received comments on this proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the 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-CBOE-2008-127 on the subject line.

⁴ 15 U.S.C. 78f(b).

⁵ 15 U.S.C. 78f(b)(5).

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-CBOE-2008-127. 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 Section, 100 F Street, NE., Washington, DC 20549-1090. Copies of the filing will also be available for inspection and copying at the Exchange's principal office. 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-CBOE-2008-127 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31148 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59147; File No. SR-CBOE-2008-123]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change To Adopt a Trade, Flash and Cancel Order Type for CBSX

December 22, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

⁶ 17 CFR 200.30-3(a)(12).

("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 3, 2008, Chicago Board Options Exchange, Incorporated ("CBOE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The filing proposes to adopt a Trade, Flash and Cancel order type for the CBOE Stock Exchange ("CBSX"). The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.org/legal>), at the Exchange's Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 IV 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

The purpose of this proposed rule change is to revise CBSX Rule 51.8 to adopt a Trade, Flash and Cancel order type. This is a market or marketable limit order to buy or sell that is to be executed in whole or in part on CBSX immediately and automatically after it is received by the CBSX System without delay for any purpose except that it will be electronically exposed pursuant to Rule 52.6 prior to cancellation. Rule 52.6 provides that market or limit orders shall not be executed at a price that would cause a trade-through of a Protected Quotation as defined in Rule 611 of Regulation NMS; instead, these

orders are "flushed" to CBSX Traders³ for potential execution at a price that would not cause a trade-through.⁴ This new order type would allow users to send orders to CBSX for execution even when CBSX is not the NBBO without requiring CBSX to seek an NBBO fill for these orders at away trading centers when price improvement on CBSX is not achieved. Thus, users can seek fills on CBSX while maintaining control over routing.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act⁵ in general and furthers the objectives of Section 6(b)(5) of the Act⁶ in particular in that, by offering users an enhanced price improvement feature and greater control over order routing, it is designed to promote just and equitable principles of trade, and serve to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and

³ "CBSX Trader" is defined in CBOE Rule 50.1. See e-mail from Angelo Evangelou, Assistant General Counsel, CBOE, to Andrew Madar, Attorney-Advisor, Commission, dated December 12, 2008.

⁴ If a flash responder attempts to trade against the order by matching the flash price (the NBBO price at the time the order was received by the CBSX System), the order will be executed unless the system determines at the point of execution that the flash price is worse than a revised NBBO in which case the order will be cancelled. See e-mail from Angelo Evangelou, Assistant General Counsel, CBOE, to Michael J. Gaw, Assistant Director, and Andrew Madar, Attorney-Advisor, Commission, dated December 19, 2008.

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

publishes its reasons for so finding, or (ii) as to which CBOE consents, the Commission will:

(A) by order approve such proposed rule change; or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the 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-CBOE-2008-123 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2008-123. 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of CBOE. 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 publicly available. All submissions should refer to File Number SR-CBOE-2008-123 and

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

Florence E. Harmon,
Acting Secretary.

[FR Doc. E8-31149 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59160; File No. SR-FINRA-2008-062]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Adopt FINRA Rule 2267 (Investor Education and Protection) in the Consolidated FINRA Rulebook

December 23, 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 December 11, 2008, the Financial Industry Regulatory Authority, Inc. (“FINRA”) (f/k/a National Association of Securities Dealers, Inc. (“NASD”)) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to adopt new FINRA Rule 2267 (Investor Education and Protection) based on NASD Rule 2280. The proposed rule change would require member firms, with certain exceptions, to provide customers with FINRA’s Web site address and information regarding FINRA’s BrokerCheck program at least once every calendar year. The text of the proposed rule change is attached as Exhibit 5.³

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As part of the process of developing a new consolidated rulebook (“Consolidated FINRA Rulebook”),⁴ FINRA is proposing to adopt a new FINRA rule based on NASD Rule 2280 (Investor Education and Protection). The proposed rule would require member firms, with certain exceptions, to provide customers with FINRA’s Web site address and information regarding FINRA’s BrokerCheck program at least once every calendar year.

NASD Rule 2280 currently applies to all member firms that carry customer accounts and hold customer funds or securities. The Rule requires that each such member firm provide its customers with the following information in writing not less than once every calendar year: (1) The “Public Disclosure Program” hotline number; (2) the NASD Regulation Web site address; and (3) a statement regarding the availability of an investor brochure that includes information describing the “Public Disclosure Program.” There is no comparable Incorporated NYSE Rule.

The proposed rule would apply to all member firms, with two general exceptions: (1) a firm that does not have customers or (2) an introducing firm that is party to a carrying agreement where the carrying firm member complies with the Rule.

Unlike NASD Rule 2280, the proposed rule would apply to member

firms that conduct a limited business with customers, such as mutual fund distributors and member firms that deal solely with direct participation programs (“DPPs”). These member firms would be required to comply with the rule and provide the disclosures to their customers at least once every calendar year. To the extent such firms are parties to a carrying agreement and the carrying firm member complies on their behalf, these firms would be excepted from the requirements of the proposed rule.

In December 2003, FINRA announced that its “Public Disclosure Program” would thereafter be known as “BrokerCheck.” Accordingly, the proposed rule would include references to “BrokerCheck” rather than the “Public Disclosure Program”. Additionally, the proposed rule would include references to the FINRA Web site address rather than the NASD Regulation Web site address. Lastly, the proposed rule would clarify that the information required under the rule may be provided electronically to customers.⁵

FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice* to be published no later than 90 days following Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,⁶ which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that, by adopting the investor education and protection rule as a FINRA rule, the proposed rule change will help to ensure that customers continue to receive written information regarding FINRA’s BrokerCheck program.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA 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.

⁵ See NASD *Notice to Members* 98-3 (Electronic Delivery of Information Between Members and Their Customers). This *Notice* sets forth the policy applicable to electronic delivery of information between member firms and their customers as permitted or required by NASD rules.

⁶ 15 U.S.C. 78o-3(b)(6).

⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The Commission notes that while provided in Exhibit 5 to the filing, the text of the proposed rule change is not attached to this notice but is available at FINRA, the Commission’s Public Reference Room, and at <http://www.finra.org>.

⁴ The current FINRA rulebook includes, in addition to FINRA Rules, (1) NASD Rules and (2) rules incorporated from NYSE (“Incorporated NYSE Rules”) (together, the NASD Rules and Incorporated NYSE Rules are referred to as the “Transitional Rulebook”). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (“Dual Members”). For more information about the rulebook consolidation process, see FINRA *Information Notice*, March 12, 2008 (Rulebook Consolidation Process).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

In May 2008, FINRA published *Regulatory Notice* 08-26 (Proposed Consolidated FINRA Rule Addressing Investor Education and Protection) requesting comment on the proposed rule change. A copy of the *Regulatory Notice* is attached as Exhibit 2a to this rule filing.⁷ The comment period expired on June 13, 2008. Nine comment letters were received in response to the *Regulatory Notice*. Copies of the comment letters, and a list of the commenters, are attached as Exhibit 2b to this rule filing.⁸

Certain commenters believe that the proposed rule should not apply to institutional customers of a member. One commenter⁹ notes that the proposed rule would continue to benefit retail investors but an exception should be provided for member firms that predominately transact business with institutional investors because these customers do not require the same levels of disclosure as retail investors. If FINRA pursues the rule change as currently proposed, the commenter requests that the required disclosures be made to institutional investors only at the time of account opening instead of once every calendar year. A second commenter¹⁰ requests that the proposed rule state expressly that member firms are not required to provide such items of information to "institutional accounts" as defined in NASD Rule 3110(c)(4) or any successor rule thereto. Another commenter,¹¹ a small introducing broker doing business solely with "sophisticated municipal market professionals" and without any retail customers, requests clarification as to whether the rule applies to its business.

NASD Rule 2280 does not provide an exemption for institutional customers, and FINRA continues to believe that institutional customers may benefit from the receipt of the information required by the proposed rule. Thus, at this time, FINRA has not included an institutional exemption in the proposed FINRA rule.

⁷ The Commission notes that while provided in Exhibit 2a to the filing, the *Regulatory Notice* is not attached to this notice.

⁸ All references to commenters under this Item are to the commenters as listed in Exhibit 2b. (The Commission notes that Exhibit 2b is not attached to this notice.)

⁹ UBS.

¹⁰ Baum.

¹¹ Gilboy.

One commenter¹² objects to the scope of the proposed rule stating that the rule should not apply to firms that do not carry customer accounts and do not hold customer funds or securities. The commenter fails to see the benefit of providing this information to customers who have no funds or securities being held with the member firm and believes the proposed rule is unclear in its application to firms that do not carry customer funds or securities. The commenter requests that FINRA retain the exemption in current NASD Rule 2280(b) for these types of firms. If FINRA pursues the rule change as currently proposed, the commenter requests that FINRA clarify which offerees or purchasers of DPPs must receive the annual disclosures. The commenter suggests an alternative proposal to require the disclosures in the subscription documents for future DPPs without an annual requirement or a look-back to any closed offerings.

FINRA understands the noted concerns and believes that if the customer relationship does not extend beyond the offering, then a subsequent annual notice is not needed. However, in such instances, the member must provide the customer with the disclosures during the time a customer relationship exists.

One commenter¹³ notes that variable annuity issuers typically distribute their products through a principal underwriter (a registered broker-dealer) that enters into selling agreements with other member firms ("selling firms"). The commenter believes that the purchaser of the variable annuity contract should only be viewed as a customer of the selling firm and that the principal underwriter should be able to rely on the exception in the proposed rule for a firm with "no customers." The commenter further seeks clarification as to whether a selling firm may rely on appropriate disclosure in a variable annuity prospectus.

FINRA agrees that a purchaser of a variable annuity contract generally may be viewed as the customer of the selling firm and not of the principal underwriter, for purposes of complying with the proposed rule. However, although the rule does not prescribe the manner in which the annual disclosures must be provided to customers, the selling firm would not be permitted to provide such disclosures in the variable annuity prospectus. FINRA does not believe that such manner of delivery is sufficiently prominent so as to provide customers with the requisite

information regarding BrokerCheck. In contrast, in response to a separate commenter,¹⁴ FINRA believes that such disclosures may be included on periodic account statements and/or trade confirmations.

According to one commenter,¹⁵ the proposed rule is unnecessary because customers do not value receiving such information. The commenter questions the usefulness of providing this notice to customers. FINRA, however, believes that the proposed rule, like its predecessor NASD Rule 2280, serves an important regulatory purpose as it provides customers with information regarding the availability and purpose of the BrokerCheck program.

Another commenter¹⁶ requests that the proposed rule have an effective date beginning in January 2009 to avoid the administrative costs of sending a separate all-client mailing at the end of the 2008 calendar year. The commenter notes that a January 1, 2009 effective date for the proposed rule would allow member firms to combine the proposed disclosures in a mailing with the required SIPC written disclosures for 2009,¹⁷ since most member firms have already sent the SIPC disclosures for the 2008 calendar year. In this regard, FINRA notes that the proposed rule change would not become effective prior to January 1, 2009. Further, it is FINRA's view that any firm subject to NASD Rule 2280 that complies with its annual (calendar year) mailing requirement on or after January 1, 2009 but prior to the effective date of the proposed rule change (*i.e.*, the effective date of FINRA Rule 2267) will be deemed to have complied with FINRA Rule 2267 for the 2009 calendar year.

Two commenters¹⁸ submitted letters that are outside the scope of the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

¹⁴ Baum.

¹⁵ FFSI.

¹⁶ MMLISI.

¹⁷ See NASD Rule 2342.

¹⁸ FSI and Wachovia.

¹² Kinkade.

¹³ Sutherland.

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the 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-FINRA-2008-062 on the subject line.

Paper Comments

- Send paper comments in triplicate to Florence E. Harmon, Acting Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-FINRA-2008-062. 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 FINRA. 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-FINRA-2008-062 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31204 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59159; File No. SR-ISE-2008-97]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Amendment of the International Securities Exchange Holdings, Inc.'s Certificate of Incorporation

December 23, 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 December 23, 2008, the International Securities Exchange, LLC (the "Exchange" or "ISE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. ISE has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(3) thereunder,⁴ which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to make technical changes to the certificate of incorporation (the "Certificate of Incorporation") of its parent, International Securities Exchange Holdings, Inc. ("Holdings"), which will be adopted in connection with a corporate transaction (the "Transaction"), in which the ISE Stock Exchange, LLC ("ISE Stock"), a Delaware limited liability company, will merge with and into Maple Merger Sub, LLC ("Maple Merger Sub"), a Delaware limited liability company and a wholly owned subsidiary of Direct Edge

Holdings LLC ("Direct Edge"), with Maple Merger Sub being the surviving entity.

Certificate of Incorporation

The Exchange is proposing to make a technical change to the Certificate of Incorporation to: (1) Correct the date of incorporation; (2) correct the address of Holdings' registered address in the state of Delaware; and (3) adopt the attestation language on the signature page. Specifically, the title of the document, Article FIRST and Article SECOND of the Certificate of Incorporation and the attestation language would be amended or adopted, as applicable, to read in its entirety as follows:

Amended and Restated Certificate of Incorporation of International Securities Exchange Holdings, Inc.

First: The name of the corporation is International Securities Exchange Holdings, Inc. (the "Corporation"). The Corporation was incorporated on November 16, 2004 by filing its Certificate of Incorporation with the Secretary of State of the State of Delaware under the name International Securities Exchange Holdings, Inc.

Second: The address of the Corporation's registered office in the State of Delaware is 160 Greentree Drive, Suite 101, in the City of Dover, County of Kent, Delaware 19904. The name of its registered agent at such address is National Registered Agents, Inc.

* * * * *

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been duly adopted in accordance with the provisions of Sections 242 and 245 of the DGCL and has been executed by a duly authorized officer of the Corporation this 23rd day of December, 2008.

Name: _____

Title: _____

The text of the proposed rule change is available on the Exchange's Web site <http://www.ise.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 19b-4(f)(3).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On December 22, 2008, the Commission approved a rule filing submitted by the Exchange in connection with the Transaction⁵ which included the Certificate of Incorporation. The purpose of this rule filing is to make technical changes to the Certificate of Incorporation necessary to permit the Exchange and Holdings to effect the Transaction. The Exchange is proposing to make technical changes to the Certificate of Incorporation: (1) Correct the date of incorporation; (2) correct the address of Holdings' registered address in the state of Delaware; and (3) adopt attestation language on the signature page.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(1) that an exchange be so organized so as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and (subject to any rule or order of the Commission pursuant to Section 17(d) or 19(g)(2) of the Exchange Act) to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder and the rules of the exchange. The Exchange also believes this proposed rule change furthers the objective of Section 6(b)(5) that an exchange have rules that, among other things, are designed to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. In particular, the proposed rule change will allow the Exchange to effect the Transaction, which was approved by the Commission on December 22, 2008.⁶

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose 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 solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act⁷ and Rule 19b-4(f)(3)⁸ thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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-ISE-2008-97 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-ISE-2008-97. 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of ISE. 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 publicly available. All submissions should refer to File Number SR-ISE-2008-97 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31192 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59149; File No. SR-NASDAQ-2008-101]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Adopt a Policy Relating to Its Treatment of Trade Reports That It Determines To Be Inconsistent With the Prevailing Market Retroactive to September 1, 2008

December 23, 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 December 19, 2008, The NASDAQ Stock Market LLC ("Nasdaq") 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 Nasdaq. The Commission is publishing this notice and order to solicit comments on the proposed rule change from interested persons.

⁵ Release No. 34-59135 (December 22, 2007); File No. SR-ISE-2008-85.

⁶ See footnote 5.

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 19b-4(f)(3).

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes that in conjunction with its previous filing to adopt a policy relating to its treatment of trade reports that it determines to be inconsistent with the prevailing market, to make such policy retroactive to September 1, 2008. The Exchange does not expect that the proposed rule change will have any direct effect, or significant indirect effect, on any other Exchange rule in effect at the time of this filing.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item III below, and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Trades in listed securities occasionally occur at prices that deviate from prevailing market prices and those trades sometimes establish a high, low or last sale price for a security that does not reflect the true market for the security. This filing, which is substantially similar to the New York Stock Exchange's ("NYSE") recent filing, seeks to address such instances of "aberrant" trades.³

The Exchange proposes that its policy in this regard shall be to contact the listing exchange (if Nasdaq is not the listing exchange) and other markets (in the case of executions that take place across multiple markets) to determine if any erroneous trade reports were filed. If not, or in the case of non-unlisted trading privilege trades, if Nasdaq determines the trade price of a trade through Nasdaq is inconsistent with the prevailing market for the security after considering the factors outlined herein, the Exchange may make the determination to append an indicator (an "Aberrant Report Indicator") to the trade.

³ See Securities Exchange Act Release No. 58736 (October 6, 2008), 73 FR 60380 (October 10, 2008) (SR-NYSE-2008-91). The Exchange notes that these proposed policies relating to the Exchange's treatment of trade reports that it determines to be inconsistent with the prevailing market are substantially similar to the NYSE's proposed policies.

Nasdaq trades stocks listed on its own market and trades on an unlisted trading privilege ("UTP") basis securities listed on other markets. Nasdaq operates the securities information processor ("SIP"), which processes trade and quote information for the Nasdaq UTP Plan ("Nasdaq SIP"). The Securities Industry Automation Corporation ("SIAC") serves as the securities information processor for the CTA Plan and processes trade and quote information for trades in non-Nasdaq listed securities. The Nasdaq SIP and the Consolidated Tape Association ("CTA") offer each participant in the Nasdaq UTP and CTA Plan the discretion to append to the Aberrant Report Indicator to a trade report to indicate that the market believes that the trade price in a trade executed on that market does not accurately reflect the prevailing market for the security.⁴

During the course of surveillance by the Exchange or as a result of notification by another market, listed company or market participant, the Exchange may become aware of trade prices that do not accurately reflect the prevailing market for a security. In such a case, the Exchange proposes to adopt as policies that it:

- i. May determine to append an Aberrant Report Indicator to any trade report with respect to any trade executed on the Exchange that the Exchange determines to be inconsistent with the prevailing market; and
- ii. Shall discourage vendors and other data recipients from using prices to which the Exchange has appended the Aberrant Report Indicator in any calculation of the high, low or last sale price of a security.

The Exchange notes that although this filing is substantially similar to the NYSE's recent filing, the NYSE filing seeks retroactive application of their proposal to January 1, 2007.⁵ Nasdaq seeks retroactive application to September 1, 2008 for this proposal. This proposal applies the same guidelines and considers the same factors during the retroactive period as set forth in Nasdaq's companion filing,⁶ which is substantially identical to this one except applicable to trades following that filing's immediate effectiveness.

Retroactive application is warranted in this instance given the unprecedented market volatility and

⁴ The CTA recommends that data recipients should exclude the price of any trade to which the Aberrant Report Indicator has been appended from any calculation of the high, low and last sale prices for the security.

⁵ *Supra* note 3.

⁶ See SR-NASDAQ-2008-100.

accurate trade reporting issues that all market centers experienced beginning in September 2008. Therefore, the Exchange proposes it should be permitted to act retroactively to append the Aberrant Report Indicator to trades that do not accurately reflect the prevailing market for a security commencing as of September 1, 2008.

The Exchange will urge vendors to disclose the exclusion from high, low or last sale price data of any trades with an Aberrant Report Indicator and exclude them from high, low or last sale price information they disseminate and to provide to data users an explanation of the parameters used in the Exchange's aberrant trade policy. Upon initial adoption of the Aberrant Report Indicator, the Exchange will contact all of its listed companies via a Head Trader Alert to explain the aberrant trade policy and that the underlying trades remain valid and will clear. In the event the trade relates to a Nasdaq-listed security, Nasdaq's Market Intelligence Desk will inform the affected listed company that these are still valid trades in that they were executed and not unwound as in the case of a clearly erroneous trade.

While SIAC, on behalf of the CTA Plan, and the Nasdaq SIP, on behalf of the Nasdaq UTP Plan, disseminate their own calculations of high, low and last sale prices, vendors and other data recipients—and not the Exchange—frequently determine their own methodology by which they wish to calculate high, low and last sale prices. Therefore, the Exchange shall endeavor to explain to those vendors and other data recipients the deleterious effects that can result from including in the calculations a trade to which the Aberrant Report Indicator has been appended.

In making the determination to append the Aberrant Report Indicator, the Exchange shall consider all factors related to a trade, including, but not limited to, the following:

- Material news released for the security;
- Suspicious trading activity;
- System malfunctions or disruptions;
- Locked or crossed markets;
- A recent trading halt or resumption of trading in the security;
- Whether the security is in its initial public offering;
- Volume and volatility for the security;
- Whether the trade price represents a 52-week high or low for the security;
- Whether the trade price deviates significantly from recent trading patterns in the security;

- Whether the trade price reflects a stock-split, reorganization or other corporate action;

- The validity of consolidated tape trades and quotes in comparison to national best bids and offers; and

- The general volatility of market conditions.

In determining whether trade prices are inconsistent with the prevailing market, the Exchange proposes that its policy shall be to follow the following general guidelines: The Exchange will review whether a trade price does not reflect the prevailing market for a security if the trade occurs during regular trading hours (*i.e.*, 9:30 a.m. to 4 p.m.) and occurs at a price that deviates from the "Reference Price" by an amount that meets or exceeds the following thresholds:

Trade price	Numerical threshold (percent)
Between \$0 and \$15.00	7
Between \$15.01 and \$50.00	5
In excess of \$50.00	3

The "Reference Price" refers to (a) if the primary market for the security is open at the time of the trade, the national best bid or offer for the security, or (b) if the primary market for the security is not open at the time of the trade, the first executable quote or print for the security on the primary market after execution of the trade in question. However, if the circumstances suggest that a different Reference Price would be more appropriate, the Exchange will use the different Reference Price. For instance, if the national best bid and offer for the security are so wide apart as to fail to reflect the market for the security, the Exchange might use as the Reference Price a trade price or best bid or offer that was available prior to the trade in question.

If Nasdaq determines that a trade price does not reflect the prevailing market for a security and the trade represented the last sale of the security on the Exchange during a trading session, the Exchange may also determine to remove that trade's designation as the last sale and the preceding last sale eligible trade would become the new last sale. Nasdaq may do so either on the day of the trade or at a later date, so as to provide reasonable time for the Exchange to conduct due diligence regarding the trade, including the consideration of input from markets and other market participants.

The Exchange proposes to use the Aberrant Report Indicator in accordance

with the guidelines set forth above.

Where appropriate, the Exchange may apply the Aberrant Report Indicator to trades that were reported prior to the adoption of this policy.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act,⁷ in general, and Section 6(b)(5) of the Act,⁸ in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the Aberrant Report Indicator is consistent with the protection of investors and the public interest in that the Exchange will seek to ensure a proper understanding of the Aberrant Report Indicator among securities market participants by: (i) Urging vendors to disclose the exclusion from high, low or last sale price data of any aberrant trades excluded from high, low or last sale price information they disseminate and to provide to data users an explanation of the parameters used in the Exchange's aberrant trade policy; (ii) informing the affected listed company each time the Exchange or another market appends the Aberrant Report Indicator to a trade in a Nasdaq-listed stock; and (iii) reminding the users of the information that these are still valid trades in that they were executed and not unwound as in the case of a clearly erroneous trade.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal**

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the 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-2008-101 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-9303.
- All submissions should refer to File Number SR-NASDAQ-2008-101. 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 such filing also will be available for inspection and copying at the principal offices of Nasdaq. 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–2008–101 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–31150 Filed 12–31–08; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–59151; File No. SR–NASDAQ–2008–100]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Policy Relating to Its Treatment of Trade Reports That It Determines To Be Inconsistent With the Prevailing Market

December 23, 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 December 19, 2008, The NASDAQ Stock Market LLC (“Nasdaq”) 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 Nasdaq. Nasdaq has designated this proposal as eligible for immediate effectiveness pursuant to Exchange Act Rule 19b–4(f)(6). The Commission is publishing this notice and order to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to adopt a policy relating to its treatment of trade reports that it determines to be inconsistent with the prevailing market. The Exchange does not expect that the proposed rule change will have any direct effect, or significant indirect effect, on any other Exchange rule in effect at the time of this filing.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item IV below, and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Trades in listed securities occasionally occur at prices that deviate from prevailing market prices and those trades sometimes establish a high, low or last sale price for a security that does not reflect the true market for the security. This filing, which is substantially similar to the New York Stock Exchange’s (“NYSE”) recent filing, seeks to address such instances of “aberrant” trades.³

The Exchange proposes that its policy in this regard shall be to contact the listing exchange (if Nasdaq is not the listing exchange) and other markets (in the case of executions that take place across multiple markets) to determine if any erroneous trade reports were filed. If not, or in the case of non-unlisted trading privilege trades, if Nasdaq determines the trade price is inconsistent with the prevailing market for the security after considering the factors outlined herein, the Exchange may make the determination to append an indicator (an “Aberrant Report Indicator”) to the trade.

Nasdaq trades stocks listed on its own market and trades on an unlisted trading privilege (“UTP”) basis securities listed on other markets. Nasdaq operates the securities information processor (“SIP”), which processes trade and quote information for the Nasdaq UTP Plan (“Nasdaq SIP”). The Securities Industry Automation Corporation (“SIAC”) serves as the securities information processor for the CTA Plan and processes trade and quote information. The Nasdaq SIP and the Consolidated Tape Association (“CTA”) offer each participant in the Nasdaq UTP and CTA

Plan the discretion to append to the Aberrant Report Indicator to a trade report to indicate that the market believes that the trade price in a trade executed on that market does not accurately reflect the prevailing market for the security.⁴

During the course of surveillance by the Exchange or as a result of notification by another market, listed company or market participant, the Exchange may become aware of trade prices that do not accurately reflect the prevailing market for a security. In such a case, the Exchange proposes to adopt as policies that it:

- i. May determine to append an Aberrant Report Indicator to any trade report with respect to any trade executed on the Exchange that the Exchange determines to be inconsistent with the prevailing market; and
- ii. Shall discourage vendors and other data recipients from using prices to which the Exchange has appended the Aberrant Report Indicator in any calculation of the high, low or last sale price of a security.

The Exchange will urge vendors to disclose the exclusion from high, low or last sale price data of any trades with an Aberrant Report Indicator and exclude them from high, low or last sale price information they disseminate and to provide to data users an explanation of the parameters used in the Exchange’s aberrant trade policy. Upon initial adoption of the Aberrant Report Indicator, the Exchange will contact all of its listed companies via a Head Trader Alert to explain the aberrant trade policy and that the underlying trades remain valid and will clear. In the event the trade relates to a Nasdaq-listed security, Nasdaq’s Market Intelligence Desk will inform the affected listed company that these are still valid trades in that they were executed and not unwound as in the case of a clearly erroneous trade.

While SIAC, on behalf of the CTA Plan, and the Nasdaq SIP, on behalf of the Nasdaq UTP Plan, disseminate their own calculations of high, low and last sale prices, vendors and other data recipients—and not the Exchange—frequently determine their own methodology by which they wish to calculate high, low and last sale prices. Therefore, the Exchange shall endeavor to explain to those vendors and other data recipients the deleterious effects that can result from including in the calculations a trade to which the

³ See Securities Exchange Act Release No. 58736 (October 6, 2008), 73 FR 60380 (October 10, 2008) (SR-NYSE–2008–91). The Exchange notes that these proposed policies relating to the Exchange’s treatment of trade reports that it determines to be inconsistent with the prevailing market are substantially similar to the NYSE’s proposed policies.

⁴ The CTA recommends that data recipients should exclude the price of any trade to which the Aberrant Report Indicator has been appended from any calculation of the high, low and last sale prices for the security.

⁹ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

Aberrant Report Indicator has been appended.

In making the determination to append the Aberrant Report Indicator, the Exchange shall consider all factors related to a trade, including, but not limited to, the following:

- Material news released for the security;
- Suspicious trading activity;
- System malfunctions or disruptions;
- Locked or crossed markets;
- A recent trading halt or resumption of trading in the security;
- Whether the security is in its initial public offering;
- Volume and volatility for the security;
- Whether the trade price represents a 52-week high or low for the security;
- Whether the trade price deviates significantly from recent trading patterns in the security;
- Whether the trade price reflects a stock-split, reorganization or other corporate action;
- The validity of consolidated tape trades and quotes in comparison to national best bids and offers; and
- The general volatility of market conditions.

In determining whether trade prices are inconsistent with the prevailing market, the Exchange proposes that its policy shall be to follow the following general guidelines: The Exchange will review whether a trade price does not reflect the prevailing market for a security if the trade occurs during regular trading hours (*i.e.*, 9:30 a.m. to 4 p.m.) and occurs at a price that deviates from the "Reference Price" by an amount that meets or exceeds the following thresholds:

Trade price	Numerical threshold (percent)
Between \$0 and \$15.00	7
Between \$15.01 and \$50.00	5
In excess of \$50.00	3

The "Reference Price" refers to (a) if the primary market for the security is open at the time of the trade, the national best bid or offer for the security, or (b) if the primary market for the security is not open at the time of the trade, the first executable quote or print for the security on the primary market after execution of the trade in question. However, if the circumstances suggest that a different Reference Price would be more appropriate, the Exchange will use the different Reference Price. For instance, if the national best bid and offer for the security are so wide apart as to fail to

reflect the market for the security, the Exchange might use as the Reference Price a trade price or best bid or offer that was available prior to the trade in question.

If Nasdaq determines that a trade price does not reflect the prevailing market for a security and the trade represented the last sale of the security on the Exchange during a trading session, the Exchange may also determine to remove that trade's designation as the last sale and the preceding last sale eligible trade would become the new last sale. Nasdaq may do so either on the day of the trade or at a later date, so as to provide reasonable time for the Exchange to conduct due diligence regarding the trade, including the consideration of input from markets and other market participants.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act,⁵ in general, and Section 6(b)(5) of the Act,⁶ in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the Aberrant Report Indicator is consistent with the protection of investors and the public interest in that the Exchange will seek to ensure a proper understanding of the Aberrant Report Indicator among securities market participants by: (i) Urging vendors to disclose the exclusion from high, low or last sale price data of any aberrant trades excluded from high, low or last sale price information they disseminate and to provide to data users an explanation of the parameters used in the Exchange's aberrant trade policy; (ii) informing the affected listed company each time the Exchange or another market appends the Aberrant Report Indicator to a trade in an Nasdaq-listed stock; and (iii) reminding the users of the information that these are still valid trades in that they were executed and not unwound as in the case of a clearly erroneous trade.

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act⁷ and Rule 19b-4(f)(6) thereunder,⁸ Nasdaq has designated this proposal as one that effects a change that: (A) Does not significantly affect the protection of investors or the public interest; (B) does not impose any significant burden on competition; and (C) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

A proposed rule change filed under 19b-4(f)(6) normally may not become operative for 30 days after the date of filing.⁹ However, Rule 19b-4(f)(6)(iii)¹⁰ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. Nasdaq has requested that the Commission waive the 30-day operative delay and designate the proposed rule change to become operative upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal is substantially similar to a proposal previously approved by the Commission.¹¹ The Commission believes that Nasdaq's proposal to append an Aberrant Report Indicator to certain trade reports is a reasonable means to alert investors and others that Nasdaq believes that the trade price for a trade executed in its

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(6).

⁹ 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. Nasdaq has satisfied this requirement.

¹⁰ *Id.*

¹¹ See Securities Exchange Act Release No. 58736 (October 6, 2008), 73 FR 60380 (October 10, 2008) (SR-NYSE-2008-91).

market does not accurately reflect the prevailing market for the security. In addition, the Commission notes that Nasdaq will use objective numerical thresholds in determining whether a trade report is eligible to have an Aberrant Trade Indicator appended to it. The Commission further notes that Nasdaq's appending the Aberrant Trade Indicator to a trade report has no effect on the validity of the underlying trade. Finally, waiving the 30-day operative delay will allow Nasdaq to apply the proposed change to future aberrant trades immediately.¹² Based on the above, the Commission designates the proposal to become operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in the furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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-2008-100 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-2008-100. 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. 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-2008-100 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8-31191 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-59163; File No. SR-NASDAQ-2008-097]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by The NASDAQ Stock Market LLC Adopting a Limited Exemption From OATS Order Data Recordation Requirements for Registered Options Market Makers

December 24, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on December 12, 2008, The NASDAQ Stock Market LLC ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to adopt a limited exemption from OATS order data recordation requirements for Bona Fide Hedging Transactions in Nasdaq-listed equities that are transacted by Nasdaq members that are registered market makers in standardized options.

The text of the proposed rule change is below. Proposed new language is in *italics*; proposed deletions are in [brackets].³

* * * * *

6951. Definitions

For purposes of the Rule 6950 Series:

(a)-(h) No change.

(i) "Order" shall mean any oral, written, or electronic instruction to effect a transaction in an equity security listed on The Nasdaq Stock Market that is received by a member from another person for handling or execution, or that is originated by a department of a member for execution by the same or another member, other than any such instruction to effect (1) a proprietary transaction originated by a trading desk in the ordinary course of a member's market making activities *in a Nasdaq-listed equity security* or (2) effect a Bona Fide Hedge Transaction involving a Nasdaq-listed equity security originated by a trading desk in the ordinary course of the member's options market making activities.

(j)-(n) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to modify its OATS rules to adopt a limited exemption from OATS order recordation requirements for bona fide hedging transactions in Nasdaq-listed equity securities that are part of a Nasdaq member's market

¹² For purposes only of waiving the 30-day operative delay, the Commission has considered the impact of the proposed rule on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

³ Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at <http://nasdaq.complinet.com>.

making activity in options. The proposal applies to options transaction on any option market in any standardized option made available for clearing through the Options Clearing Corporation.

OATS is an integrated audit trail of order, quote, and trade information for Nasdaq equity securities used to recreate events in the life cycle of orders and more completely monitor the trading practices of member firms. The basis for OATS is customer protection through the transparency of the executions of customer orders in equity securities. OATS was designed to provide an accurate, time-sequenced record of orders and transactions, beginning with the receipt of an equity order at the first point of contact between the broker-dealer and the customer or counterparty and further documenting the life of the equity order through the process of execution.

Consistent with that basis, there is currently no OATS requirement with respect to options listed on the NASDAQ Options Market. Additionally, there are currently exemptions from OATS requirements for orders entered by market makers in Nasdaq securities and by proprietary trading firms because such orders are not submitted on behalf of customers and therefore do not necessitate the customer protection provided by OATS.

The proposed rule change does not impact the customer protection orientation of OATS since, by definition, bona fide hedging transactions in equity securities that are undertaken by options market makers do not involve customer orders in those equity securities. Rather, bona fide hedging transactions in equity securities are undertaken by an options market maker to hedge against the firm risk that it creates through its conduct as a registered options market maker. Accordingly, submitting bona fide hedging transactions to OATS recording requirements provides no customer protection or equivalent regulatory benefit. It is also very expensive for firms that are not currently FINRA members or that do not currently trade NASDAQ equities to develop and maintain the compliance systems and compliance staff required to continuously monitor the daily transmission of OATS data.

Additionally, information regarding bona fide hedging transactions retained by a registered NOM market maker is otherwise available to FINRA and Nasdaq Regulation through Nasdaq's electronic delivery systems, upon request. This information includes trade reporting data, including order time and

sales data captured by the Nasdaq system.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁴ in general, and with Section 6(b)(5) of the Act,⁵ in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

⁴ 15 U.S.C. 78f.

⁵ 15 U.S.C. 78f(b)(5).

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-2008-097 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-2008-097. 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, 100 F Street, NE., Washington, DC 20549, 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-2008-097 and should be submitted on or before January 23, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Florence E. Harmon,
Acting Secretary.

[FR Doc. E8-31203 Filed 12-31-08; 8:45 am]

BILLING CODE 8011-01-P

⁶ 17 CFR 200.30-3(a)(12).

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****Environmental Impact Statement;
Pierce County, WA**

AGENCY: Federal Highway Administration (FHWA), Washington State Department of Transportation (WSDOT).

ACTION: Notice of Intent to prepare an Environmental Impact Statement.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed highway project on State Route 302 (SR) from Key Peninsula Highway to SR 16 in Pierce County, Washington.

FOR FURTHER INFORMATION CONTACT: Wendy L. McAbee, Olympic Region Area Engineer, Federal Highway Administration, 711 S. Capital Way, Suite 501, Olympia, Washington 98507, (360) 753-9025, e-mail: wendy.mcabee@dot.gov or contact John P. Donahue, Project Manager, Washington State Department of Transportation, 5720 Capitol Boulevard, Tumwater, Washington 98501, (360) 357-2788, e-mail: donahjo@wsdot.wa.gov.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with WSDOT, will prepare an Environmental Impact Statement (EIS) on a proposal to address existing and long-term safety and congestion conditions on State Route 302 (SR) corridor from Key Peninsula Highway to SR 16 in Pierce County, Washington. This corridor is approximately 7.6 miles long, and is located between milepost 10.55 and milepost 16.87 on SR 302, and milepost 15.85 and milepost 17.13 on SR 302 Spur.

Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand and improve connectivity between communities on the Key Peninsula and State Route 16. The proposed project would provide an efficient and functional transportation route along the SR 302 corridor between SR 302 at Key Peninsula Highway and SR 16. The proposed action will also increase the level of safety for travelers.

State Route 302 from SR 3 to SR 16 was studied in 1993 to determine alternatives for improving the corridor. The study recommended several potential alternatives and performing an EIS. Traffic information gathered in 2007 revealed dramatic differences in safety and congestion statistics east and west of Key Peninsula Highway and SR

302. As a result, the logical study endpoints of the project were found to lie between Key Peninsula Highway and SR 16. Multiple opportunities have been provided for public involvement in defining the project purpose and need and determining the range of reasonable alternatives to be considered for the project in the EIS. WSDOT is currently in the middle of an extensive alternatives screening process in order to evaluate a comprehensive list of project alternatives. Further opportunities for the public to comment will be provided throughout the Environmental Impact Statement process.

Scoping letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and Local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A series of public meetings will be held throughout the environmental process. In addition, a public hearing will be held. Public notice will be given of the time and place of the meetings and hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing. A formal scoping meeting with resource agencies is scheduled for January 12, 2009. Resource agencies were notified 30 days prior to the meeting date. A public scoping meeting is also planned for mid-January 2009.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: December 23, 2008.

Wendy McAbee,

Area Engineer, Washington Division, Federal Highways Administration.

[FR Doc. E8-31198 Filed 12-31-08; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF THE TREASURY**Fiscal Service****Surety Companies Acceptable on
Federal Bonds: Argonaut Insurance
Company**

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 6 to the Treasury Department Circular 570, 2008 Revision, published July 1, 2008, at 73 FR 37644.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874-6850.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued under 31 U.S.C. 9305 to the following company:

Argonaut Insurance Company (NAIC #19801). BUSINESS ADDRESS: 10101 Reunion Place, Suite 500, San Antonio, TX 78216. PHONE: (800) 470-7958. UNDERWRITING LIMITATION b/: \$46,666,000. SURETY LICENSES c/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WY. INCORPORATED IN: Illinois.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 ("Circular"), 2008 Revision, to reflect this addition.

Certificates of Authority expire on June 30th each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (see 31 CFR part 223). A list of qualified companies is published annually as of July 1st in the Circular, which outlines details as to the underwriting limitations, areas in which companies are licensed to transact surety business, and other information.

The Circular may be viewed and downloaded through the Internet at <http://www.fms.treas.gov/c570>.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: December 19, 2008.

Vivian L. Cooper,

Director, Financial Accounting and Services Division.

[FR Doc. E8-31077 Filed 12-31-08; 8:45 am]

BILLING CODE 4810-35-M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Name Change: FOLKSAMERICA REINSURANCE COMPANY (NAIC #38776)

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 7 to the Treasury Department Circular 570; 2008 Revision, published July 1, 2008, at 73 FR 37644.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874-6850.

SUPPLEMENTARY INFORMATION:

FOLKSAMERICA REINSURANCE COMPANY (NAIC #38776), a New York corporation, has formally changed its name to WHITE MOUNTAINS REINSURANCE COMPANY OF AMERICA, effective July 8, 2008. The Company was last listed as an acceptable surety on Federal bonds at 73 FR 37644, July 1, 2008.

A Certificate of Authority as an acceptable surety on Federal bonds, dated today, is hereby issued under Sections 9304 to 9308 of Title 31 of the United States Code, to WHITE MOUNTAINS REINSURANCE COMPANY OF AMERICA. This new Certificate replaces the Certificate of Authority issued to the Company under its former name. The underwriting limitation of \$92,661,000 established for the Company as of July 1, 2008, remains unchanged until June 30, 2009. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 ("Circular"), 2008 Revision, to reflect this change.

Certificates of Authority expire on June 30th each year, unless revoked

prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list of qualified companies is published annually as of July 1st in the Circular, which outlines details as to underwriting limitations, areas in which companies are licensed to transact surety business, and other information.

The Circular may be viewed and downloaded through the Internet at <http://www.fms.treas.gov/c570>.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: December 19, 2008.

Vivian L. Cooper,

Director, Financial Accounting and Services Division.

[FR Doc. E8-31078 Filed 12-31-08; 8:45 am]

BILLING CODE 4810-35-M



Federal Register

**Friday,
January 2, 2009**

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 424

**Medicare Program; Surety Bond
Requirement for Suppliers of Durable
Medical Equipment, Prosthetics, Orthotics,
and Supplies (DMEPOS); Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6006-F]

RIN 0938-AO84

Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: Consistent with section 4312(a) of the Balanced Budget Act of 1997 (BBA), this final rule implements section 1834(a)(16) of the Social Security Act (the Act) by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to furnish CMS with a surety bond.

DATES: *Effective Date:* These regulations are effective on March 3, 2009.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302.

SUPPLEMENTARY INFORMATION:

I. Background

A. General and Legislative History

Medicare services are furnished by two types of entities—providers and suppliers. At § 400.202, “provider” is defined as a hospital, a critical access hospital (CAH), a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency (HHA), or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. The term “provider” is also defined in sections 1861(u) and 1866(e) of the Social Security Act (the Act).

The term “supplier” is defined at section 1861(d) of the Act and includes an entity that furnishes durable medical equipment, prosthetics, orthotics, and suppliers (DMEPOS). Other supplier categories may include, for example, physicians, nurse practitioners (NPs), and physical therapists. The term “DMEPOS” encompasses the types of items included in the definition of medical equipment and supplies found

at section 1834(j)(5) of the Act. As used in this final rule, the term “supplier” refers only to a supplier of DMEPOS.

For purposes of the DMEPOS supplier standards, the term “DMEPOS supplier” is defined in § 424.57(a) as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items to Medicare beneficiaries and that meets the DMEPOS supplier standards. Those individuals or entities that do not furnish DMEPOS items but furnish other types of health care services only (for example, physician services or NP services) would not be subject to this requirement.

B. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

1. Durable Medical Equipment

The term DME is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DME those items furnished in skilled nursing facilities and hospitals (equipment furnished in those facilities is paid for as part of their routine or ancillary costs). Also, the term “DME” is included in the definition of “medical and other health services” found at section 1861(s)(6) of the Act. Furthermore, the term is defined in § 414.202 as equipment furnished by a supplier or a HHA that—

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to an individual in the absence of an illness or injury; and
- (4) Is appropriate for use in the home.

Examples of DMEPOS supplies include items such as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs.

2. Prosthetic Devices

Prosthetic devices are included in the definition of “medical and other health services” under section 1861(s)(8) of the Act. Prosthetic devices are defined in this section of the Act as “devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.” Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves. Under section

1834(h)(4)(B) of the Act, prosthetic devices do not include parenteral and enteral nutrition nutrients and implantable items payable under section 1833(t) of the Act.

3. Orthotics and Prosthetics

Section 1861(s)(9) of the Act provides for the coverage of “leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient’s physical condition.” As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as “orthotics and prosthetics.”

4. Supplies

Section 1861(s)(5) of the Act includes “surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocation” as one of the “medical and other health services” that is covered by Medicare. Other items that may be furnished by suppliers would include (among others):

- Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title, and that are furnished within a certain time period after the date of the transplant procedure as noted at section 1861(s)(2)(j) of the Act.
- Extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes as listed at section 1861(s)(12) of the Act.
- Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies included at section 1861(s)(2)(F) of the Act.
- Oral drugs prescribed for use as an anticancer therapeutic agent as specified in section 1861(s)(2)(Q) of the Act.
- Self-administered erythropoietin as described in section 1861(s)(2)(O) of the Act.

C. The January 20, 1998 Proposed Rule

In the Medicare Program; Additional Supplier Standards proposed rule published in the January 20, 1998 **Federal Register** (63 FR 2926), we proposed to reflect the changes made to section 1834 of the Act by section 4312(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33). (Section 4312(a) of the BBA amended section 1834(a) of the Act by adding paragraph (a)(16)(B), which requires a DME supplier to provide us, on a continuing basis, with a surety bond of at least \$50,000, as a condition of the issuance or renewal of a provider number. Section 1834(a)(16) of the Act, as amended by section 4312(c) of the BBA, further provides that we may also

require a surety bond from some or all providers or suppliers who furnish items or services under Medicare Part A or Part B.) In the January 20, 1998 proposed rule, we also proposed that for each tax identification number (TIN) for which a supplier billing number is issued, a DMEPOS supplier must obtain a surety bond in an amount not less than \$50,000.

On October 11, 2000, we published a final rule titled, "Medicare Program; Additional Supplier Standards (HCFA-6004-FC)" in the **Federal Register** (65 FR 60366). However, as we stated in the October 11, 2000 final rule with comment that we decided not to incorporate the provisions related to surety bonds into this final rule with comment, but rather issue the surety bond provisions as a proposed rule at a future date.

In 2003, the Congress enacted section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) which prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than 3 years earlier except under exceptional circumstances. In light of section 902 of MMA and our previous decision to issue a proposed rule, we published a proposed rule titled, "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (DMEPOS) (CMS-6006-P) in the **Federal Register** (72 FR 42001) on August 1, 2007.

II. Provisions of the Proposed Regulations

In the August 1, 2007 **Federal Register** (72 FR 42001), we proposed to implement the statutory surety bond requirement set forth in section 1834(a)(16)(B) of the Act.

Given the lapse in time between the statutory effective date (that is, section 1834 of the Act was amended by section 4312(a) of the BBA enacted on August 5, 1997) and the date of the proposed rule, we proposed to adjust the amount of the surety bond from \$50,000 in 1997 by the Consumer Price Index (CPI) resulting in a higher surety bond amount. In doing so, we proposed to adjust the initial surety bond amount of \$50,000 by the CPI and calculated that a \$50,000 surety bond in 1997 would equate to a surety bond value of \$64,907.17 in 2007. Further, we rounded the calculated value of \$64,907.17 to the nearest thousand to derive a surety bond amount of \$65,000. We proposed that establishing a \$65,000 surety bond for DMEPOS suppliers would: (1) Limit the Medicare program

risk to fraudulent DME suppliers; (2) enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; (3) ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or its designated contractor to seek payments from a surety up to the penal sum; and (4) help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers.

In § 424.57(a), we proposed to define the following terms as they are used throughout the regulation in the context of the surety bond requirements:

- Assessment.
- Authorized Surety.
- Civil money penalty.
- Government-Operated Suppliers.
- National Supplier Clearinghouse (NSC).
- Penal Sum.
- Rider.
- Sufficient evidence.
- Surety bond.
- Unauthorized Surety.
- Unpaid claim.

Although we proposed to define "unauthorized surety", we clarified that we did not envision that we would need to declare a surety to be unauthorized except on rare occasions. We anticipate that virtually every surety would provide us, upon written request, information needed to verify the identity of a bondholder, the effective date of the bond, and proof that the surety issued the bond as represented by the supplier. However, if a surety fails to comply with our request for this information, we would consider that surety as unauthorized to provide bonds to DMEPOS suppliers seeking enrollment in the Medicare program. We believe that without this provision, some sureties may not be inclined to provide information we need on a timely basis.

Furthermore, a surety is unauthorized if it had previously failed to comply with a reasonable request from us for payment against a bond. An example of a reasonable request would be a request in writing, signed by an official of CMS or its representatives, or documentation about the amount payable by the supplier. This provision would allow us to take action to prevent a surety from issuing a bond to a Medicare DMEPOS supplier in cases where we have determined that the surety failed to meet its obligations to the Medicare program.

In § 424.57, we proposed to add new (c)(26). Specifically, we proposed that—

- Section 424.57(c)(26) would specify the requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier.
- Section 424.57(c)(26)(i) would clarify the minimum requirements for a DMEPOS supplier. We specified that each Medicare-enrolled DMEPOS supplier must obtain a surety bond for each National Provider Identifier (NPI) from an authorized surety. The surety bond or government security would have had to be in the amount of \$65,000 and in the form specified by the Secretary. While we proposed to adjust the amount of the surety bond from \$50,000 in 1997 by the CPI and calculate a higher surety bond amount of \$65,000 in 2007, we did not propose to adjust the base surety bond amount by the CPI annually thereafter. However, we would consider whether any additional adjustments (increase or decrease) in the base bond amount are necessary through a future rulemaking effort.

- Section 424.57(c)(26)(i)(A) would specify that a DMEPOS supplier must submit a surety bond with its initial paper or electronic Medicare enrollment application (CMS-855S, OMB Number 0938-0685) or with its paper or electronic revalidation or reenrollment application.

- Section 424.57(c)(26)(i)(B) would specify how a change of ownership interest affects the DMEPOS supplier.

- Section 424.57(c)(26)(i)(C) would specify that a DMEPOS supplier seeking to enroll a new location must obtain a new surety bond for this new location since this new location is also required to be enumerated with a unique NPI.

- Section 457.57(c)(26)(ii) would establish an exception to the bond requirement for a DMEPOS supplier operated by a Federal, State, local, or tribal government agency if the DME supplier has provided CMS with a comparable surety bond required under State law and if the supplier does not have any unpaid claims, civil money penalties (CMPs), or assessments. However, a government-operated supplier that did not qualify for an exception would have to submit a surety bond. We have determined that an exception to the surety bond requirement for government-operated suppliers extends only to those suppliers that have a good history of paying their Medicare debts. The basis for this exception is principally that government-operated suppliers have the power to tax; therefore, it is unlikely that these DMEPOS suppliers will be

unable to pay their Medicare debts. Thus, government-operated DMEPOS suppliers, by their public nature, furnish a comparable or greater guarantee of payment than would be afforded us by a surety bond issued by a private surety.

Also, a supplier operating under a contract with a government agency but not owned and staffed by the government would not qualify for this exception. Our experience with previously published rules suggests that a government-operated entity would timely pay their Medicare debts (see the HHA surety bond final rule published in the **Federal Register** on January 5, 1998 (63 FR 315); amended by a final rule published in the **Federal Register** on March 4, 1998 (63 FR 10731); a final rule published in the **Federal Register** on June 1, 1998 (63 FR 29656); and a final rule published in the **Federal Register** on July 21, 1998 (63 FR 41171)).

• We solicited comments on whether to establish exceptions for certain types of suppliers. Specifically, we solicited the following comments:

+ Whether we should consider establishing an exception to the surety bond requirement for certain physicians and nonphysician practitioners (NPPs), such as those that occasionally furnish DMEPOS items for the convenience of their patients. While we sought comments about establishing an exception for physicians and NPPs, we were not certain about the scope of the exception that should be established for physicians and NPPs. As such, we solicited comments on how to identify whether a physician or NPP should be given an exception to the surety bond requirement. We also solicited comments on any other appropriate criteria that we should use when considering the establishment of an exception to this requirement for certain physicians and NPPs.

+ Whether we should establish an exception to the surety bond requirement for licensed pharmacists who furnish DMEPOS items for the convenience of their patients and any other appropriate criteria that we should consider in establishing an exception to this requirement for licensed pharmacists.

+ Any other appropriate criteria that we should consider in establishing an exception to this requirement for these types of suppliers.

+ Whether we should establish an exception to the surety bond requirement for large, publicly traded chain suppliers of DMEPOS and on any appropriate criteria that we should

consider in waiving this requirement for these types of suppliers.

+ The appropriate criteria that we may use for establishing exceptions for other types of DMEPOS suppliers from the requirement to purchase a surety bond.

• Section 424.57(c)(26)(iii) would specify the terms of a bond submitted by a DMEPOS supplier.

• Section 424.57(c)(26)(iv) would specify additional DMEPOS supplier bond requirements and would specify the surety's liability under the bond for unpaid claims, CMPs, or assessments that the surety is liable to us, up to a total of the full penal amount of the bond. Thus, since we proposed that surety bonds be issued in an amount equal to \$65,000, the surety is liable to us for up to \$65,000.

• Section 424.57(c)(26)(v) would specify the requirements to cancel a surety bond. Specifically, this section would allow a DMEPOS supplier to terminate or cancel a bond upon proper notice to the NSC. If another bond is submitted and there is a lapse in bond coverage, Medicare would not pay for items or services furnished during the gap in coverage, and the DMEPOS supplier would be held liable for the items or services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for the items or services). Failure by the DMEPOS supplier to submit another bond would result in the revocation of the DMEPOS supplier's Medicare billing privileges. The supplier would be required to refund the beneficiary any amounts collected for services or supplies furnished during the gap in the surety bond coverage. Finally, a supplier or surety may not make amendment to a conforming bond that will limit the scope or term of the bond in a manner resulting in the bond no longer conforming to the provisions of this regulation. Any attempt to do so may result in the revocation of the DMEPOS supplier's billing privileges and a determination that the surety is an unauthorized surety.

• Section 424.57(c)(26)(vi) would specify that the bond must provide that actions under the surety bond may be brought by our contractors or us.

• Section 424.57(c)(26)(vii) would specify that the surety must provide information regarding its physical location including its name, street address, city, state, and zip code and, if different, its mailing address, including name, post office box, city, state, and zip code.

• Section 424.57(c)(26)(viii) would specify the submission date and the term of the DMEPOS supplier bond.

• Section 424.57(c)(26)(viii)(A) would specify that each enrolled DMEPOS supplier that does not meet the criteria for an exception must submit to the NSC an initial surety bond before (60 days following the publication date of the final rule).

• Section 424.57(c)(26)(viii)(B) would specify the type of bond required to be submitted by a DMEPOS supplier under this subpart must be either a continuous bond or an annual bond, with the exception of the initial bond which may differ as specified in this section.

• Section 424.57(c)(26)(ix) would specify the loss of a DMEPOS supplier exception. A DMEPOS supplier that no longer qualifies for an exception as a government-operated DMEPOS supplier must submit a surety bond to the NSC within 60 days after it receives notice that it no longer meets the criteria for an exception.

• Section 424.57(c)(26)(x) would specify the conditions under which a DMEPOS supplier changes a surety.

• Section 424.57(c)(26)(xi) would specify who the parties are to the bond.

• Section 424.57(c)(26)(xii) would specify the effect of a DMEPOS supplier's failure to obtain and maintain a surety bond.

• Section 424.57(c)(26)(xii)(A) would specify that we may revoke the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, and maintain a surety bond as specified in this subpart and as instructed by us. The revocation is effective with the date the bond lapsed, and any payments for items or services furnished on or after that date must be repaid to us by the DMEPOS supplier.

• Section 424.57(c)(26)(xii)(B) would specify that we refuse to issue billing privileges to the DMEPOS supplier if a DMEPOS supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified in this subpart and our instructions.

• Section 424.57(c)(26)(xiii) would specify the documentation that a DMEPOS supplier must have to be in compliance with these requirements and that we may require a supplier to produce documentation demonstrating that it has a bond and that it meets the requirements of this section.

• Section 424.57(c)(26)(xiv) would specify the effect of subsequent DMEPOS supplier payments paid to us. If a surety has paid an amount to us on the basis of liability incurred under a bond and we subsequently collect from the DMEPOS supplier, in whole or in part, on the unpaid claims, CMPs, or assessments that were the basis for the surety's liability, we would reimburse

the surety the amount that we collected from the DMEPOS supplier, up to the amount paid by the surety to us, provided the surety has no other liability to us under the bond.

- Section 424.57(c)(26)(xv) would specify the effect of a review reversing an appealed determination. We would refund to the DMEPOS supplier the amount that the DMEPOS supplier paid us, to the extent that the amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

In addition, DMEPOS suppliers have the right to appeal any adverse decisions with respect to unpaid claims, CMPs or assessments. DMEPOS suppliers must use the following applicable appeals provisions specified in 42 CFR associated with each adverse determination: Part 405, subpart I (claims appeals); Part 1003 (civil money penalties); and Part 498 (Medicare participation and enrollment).

We believe that the appeals processes as they apply to DMEPOS suppliers and sureties should be addressed through a private contract between the parties. Specifically, we believe that sureties should consider requiring DMEPOS suppliers to agree to repay the surety any payments made by a Medicare contractor resulting from a DMEPOS supplier's appeal of any adverse decisions with respect to unpaid claims, CMPs, or assessments. Any such contract must be consistent with the applicable appeals processes referenced above. In determining whether a private contract is necessary, we suggest that the sureties and DMEPOS suppliers consider the following types of provisions: Appointment of representative, repayment of any bonding amounts paid to the DMEPOS supplier that were already paid by the surety and the potential cost of pursuing administrative appeals.

Furthermore, we solicited comments on requiring DMEPOS suppliers to obtain a surety bond of more than \$65,000 if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds. Specifically, we solicited comments on how to establish elevated amounts of

surety bonds for higher risk DMEPOS suppliers. We proposed to consider the option of establishing elevated amounts of the surety bond at a rate of \$65,000 per high risk factor. Also, we solicited comments on determining the high risk factors that should be used. We suggested several potential high risk factors, and solicited comments on these factors, as well as suggestions for additional factors.

We proposed to consider a \$65,000 increase in the surety bond amount for each occurrence when a DMEPOS supplier has an adverse action as specified in section 221(g)(1)(A) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA). Examples of adverse actions include, but are not limited to, Federal and State criminal convictions related to the delivery of a health care item or service; formal or official actions, such as the revocation or suspension of a license; and exclusion from participation in Federal or State health care programs. The following is an example of how high-risk criteria would be used to increase the bond amount by \$65,000 per occurrence.

- We proposed, for example, a DMEPOS supplier would be required to obtain a surety bond in the amount of \$130,000, an increase of \$65,000 from the base surety bond amount of \$65,000, if the DMEPOS supplier or any of its owners, authorized officials, or delegated officials had their billing privileges revoked within the last 10 years. If the DMEPOS supplier or any of its owners, authorized officials, or delegated officials had more than one revocation in the last 10 years, then the amount of the surety bond the DMEPOS supplier would be required to obtain would increase \$65,000 per occurrence. We proposed, for example, that a DMEPOS supplier with three different revocations during the preceding 10 years would be required to obtain a surety bond in the amount of \$260,000; \$65,000 for the base surety amount and \$195,000 (3 × \$65,000) for the multiple revocations.

In addition to the elevated risk-based model described above, we solicited comments regarding the establishment of elevated bond amounts by classifying

DMEPOS suppliers into two or three general categories such as—

- New DMEPOS supplier applicants that have no prior billing history with the Medicare program that also would be required to secure a surety bond;
- Current Medicare enrolled DMEPOS suppliers that do not have any prior history of criminal, civil or administrative sanctions for billing-related problems; and,
- Current Medicare enrolled DMEPOS supplier with a prior “adverse history” of criminal, civil or administrative sanctions for billing-related problems for which the regulation would elevate the amount of the required bond by an appropriate amount per prior sanction.

We solicited comments regarding the appropriate elevated amounts of the surety bond using this categorical approach.

We also solicited comments on whether we should establish an exception for rural DMEPOS suppliers and the appropriate criteria that we should consider in establishing an exception for rural DMEPOS suppliers.

Finally, we solicited comments on the appropriate period of time for which a DMEPOS supplier should be required to maintain a higher surety bond amount. Given the higher level of risk associated with DMEPOS suppliers that have one or more risk factors, we proposed to establish a timeframe of 5 years.

III. Analysis of and Responses to Public Comments

We received approximately 200 timely public comments in response to the August 1, 2007 proposed rule. The following is a summary of the comments received and our responses.

(Note: In order to clarify the regulations regarding surety bonds, we have made some technical changes to our proposals.)

Table 1 is provided to assist the reader in cross-referencing the proposed provision with its revised section. (For a more detailed explanation of the technical changes made to this final rule, please see section IV. of this final rule.)

TABLE 1—REDESIGNATIONS FROM PROPOSED RULE TO FINAL RULE

Subject heading	Proposed rule	Final rule
Definitions	§ 424.57(a)	§ 424.57(a)
Effective date	§ 424.57(c)(26)	§ 424.57(d)(1)
Minimum requirements for a DMEPOS supplier	§ 424.57(c)(26)(i)	§ 424.57(d)(2)
Exception to the surety bond requirement	§ 424.57(c)(26)(ii)	§ 424.57(d)(15)
Terms of the surety bond	§ 424.57(c)(26)(iii)	§ 424.57(d)(4)
Specific surety bond requirements	§ 424.57(c)(26)(iv)	§ 424.57(d)(5)
Cancellation of a bond and lapse of surety bond coverage	§ 424.57(c)(26)(v)	§ 424.57(d)(6)

TABLE 1—REDESIGNATIONS FROM PROPOSED RULE TO FINAL RULE—Continued

Subject heading	Proposed rule	Final rule
Actions under the surety bond	§ 424.57(c)(26)(vi)	§ 424.57(d)(7)
Required surety information on the surety bond	§ 424.57(c)(26)(vii)	§ 424.57(d)(8)
Submission date	§ 424.57(c)(26)(viii)	§ 424.57(d)(1)
Type of bond	§ 424.57(c)(26)(viii)	§ 424.57(d)(4)
Loss of DMEPOS supplier exception	§ 424.57(c)(26)(ix)	§ 424.57(d)(15(ii))
Change of surety	§ 424.57(c)(26)(x)	§ 424.57(d)(9)
Parties to the bond	§ 424.57(c)(26)(xi)	§ 424.57(d)(10)
Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond	§ 424.57(c)(26)(xii)	§ 424.57(d)(11)
Evidence of DMEPOS supplier's compliance	§ 424.57(c)(26)(xiii)	§ 424.57(d)(12)
Effect of subsequent DMEPOS supplier payment	§ 424.57(c)(26)(xiv)	§ 424.57(d)(13)
Effect of review reversing determination	§ 424.57(c)(26)(xv)	§ 424.57(d)(14)

A. General Comments

Comment: Numerous commenters opposed the surety bond requirement. Commenters stated that the surety bond requirement would create an additional and unnecessary burden on DMEPOS suppliers. Commenters indicated that DMEPOS suppliers have already been burdened with, among other things, continued reductions in Medicare reimbursement, competitive bidding, and accreditation. In addition, commenters stated that there is no need to impose the surety bond requirement on DMEPOS suppliers since these suppliers represent a small fraction of Medicare spending.

Response: We recognize that we have recently implemented a number of program integrity measures designed to strengthen the enrollment process and improve quality of products and services. As the commenter notes, one such initiative is accreditation. Section 302 of the MMA added section 1834(a)(20) to the Act, which mandates the establishment and implementation of quality standards for DMEPOS suppliers. All suppliers that furnish such items or services under section 1834(a)(20)(D) of the Act, as the Secretary determines appropriate, must comply with the quality standards in order to obtain and maintain Medicare billing privileges. The Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) required all DMEPOS suppliers to meet quality standards for Medicare accreditation by October 1, 2009. In addition, section 154 of the MIPPA stated that certain professionals and persons do not have to meet this deadline unless quality standards are developed specific to these professionals and persons. Section 154(b) of the MIPPA, added a new subparagraph (F) to section 1834(a)(20) of the Act. This subparagraph states that eligible professionals and other persons are exempt from meeting the October 1, 2009 accreditation deadline unless CMS

determines that the quality standards are specifically designed to apply to such professionals and persons. Eligible professionals under section 1834(a)(20)(F) of the Act include physicians (as defined in section 1861(r) of the Act), physical therapists, occupational therapists, qualified speech-language pathologists, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians, and nutritional professionals. We have designated certain individuals as falling within the category of “other persons” under the statute; these individuals include orthotists, prosthetists, opticians, and audiologists. We will work in collaboration with the medical and professional groups to develop specific quality standards.

We believe that the accreditation process will assure that Medicare beneficiaries receive quality supplies and services from eligible suppliers.

Nevertheless, we do not believe that the implementation of accreditation and other program integrity initiatives obviates the need to establish a surety bond requirement for DMEPOS suppliers, something that will help ensure that DMEPOS suppliers meet minimum financial requirements in order to participate in Medicare.

Comment: Many commenters stated that a surety bond would offer little or no additional protection to CMS since the accreditation process for DMEPOS suppliers is already providing a greater level of security. The commenters indicated that the quality standards in the accreditation process include stringent provisions that limit the risk of Medicare fraud. As a result, some of the commenters described the surety bond requirement as redundant, duplicative, unnecessary, costly, and extreme. Another commenter stated that it believes its licensure and certification status as a hand therapist and our

accreditation process are sufficient evidence of both its competence and ethical behavior. Yet another commenter stated that both initiatives should be analyzed, coordinated, and reconciled before implementation.

Response: We disagree with the commenters that a surety bond would offer little or no protection because we are in the process of implementing the accreditation requirements for DMEPOS suppliers. As already indicated, while accreditation will ensure that a DMEPOS supplier meets certain quality standards, a surety bond will ensure that DMEPOS suppliers that do not qualify for an exception to the bonding requirement meet enhanced financial requirements. Moreover, only surety bonds can be used to repay any incurred overpayments. We believe that these efforts, when combined, will have a significant impact on both the quality of products and services provided to Medicare beneficiaries, but also increase our efforts to ensure that only qualified suppliers are eligible to enroll or remain enrolled in the Medicare program.

We understand that many DMEPOS suppliers are concerned with the cumulative effect that several different statutory changes will have on suppliers of DMEPOS. We have taken this effect into consideration, and the revised impact analysis contained in this final rule accounts for the cumulative impact.

Comment: A commenter stated that it is a waste of American citizens' money to require DMEPOS suppliers that bill \$25,000 a year or less to obtain surety bonds.

Response: We disagree with the commenter. The surety bond for DMEPOS suppliers is designed to reduce the amount of money that is lost due to fraudulent or abusive billing schemes perpetrated by individuals and organizations. In addition, we do not believe that prior billing is necessarily proof of future actions.

Comment: One commenter believes that the surety bond requirement will not substantively strengthen program

integrity. The commenter stated that, although requiring suppliers to obtain a surety bond as a condition of Medicare enrollment may deter some of the more simplistic criminal fraud schemes, it is unrealistic for CMS to expect that the requirement will eliminate the most insidious type of fraudulent supplier, which is the DMEPOS supplier that initially appears to meet the minimum indicia of a legitimate business. The commenter stated that this is the type of criminal element that has consistently evaded our oversight and enforcement initiatives. Other commenters stated that the surety bond requirement is only a repayment mechanism for the Medicare program and not a true deterrent to criminal or abusive billing practices. The commenters also stated that anyone with a criminal intent, and the means to effectuate it, can bill and get paid for fraudulent claims before we have identified the fraud.

Response: We believe that the surety bond requirement is an important tool that, when used in conjunction with other efforts to reduce fraudulent or abusive behavior, will assist us in protecting the Medicare Trust Funds. While we recognize that implementing a surety bond requirement for certain DMEPOS suppliers will not deter all types of fraud and abuse perpetrated by individuals and organizations intent on committing such actions, we believe that this statutorily mandated requirement will greatly assist us in our efforts to reduce fraud and abuse by some suppliers of DMEPOS and to identify more sophisticated instances of fraudulent behavior.

Comment: One commenter stated that if fraud is located primarily in urban areas, such as Miami, Florida, and involves DMEPOS suppliers that conduct a large volume of business, then the August 1, 2007 proposed rule is misdirected because it penalizes suppliers that conduct a small volume of business in other parts of the country, such as the Midwest.

Response: We understand the concerns of the commenter, but we also recognize that fraudulent schemes are portable and can be perpetuated in any part of the country, not just urban areas. The surety bond requirement will help to ensure that certain newly enrolling DMEPOS suppliers meet financial solvency standards, as well as our established conditions for enrollment and payment.

Comment: One commenter stated that we should not impose additional costs through the surety bond requirement but should instead focus our resources on those suppliers it can readily find committing Medicare fraud and abuse.

Response: We are expanding our effort to identify, detect, and revoke the billing privileges of those DMEPOS suppliers who fail to meet the supplier standards found at § 424.57. By establishing a surety bond requirement for newly enrolling DMEPOS suppliers as well as existing DMEPOS suppliers, we believe that we will improve the quality of services received by Medicare beneficiaries, as well as establish additional program safeguards for the Medicare program.

B. Legislative Authority

Comment: One commenter stated that we have no legislative authority to implement the surety bond requirement. The commenter noted that section 902 of the MMA prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than 3 years earlier except under exceptional circumstances. The commenter indicated that we did not finalize the January 20, 1998 proposed rule within the prescribed timeframe. As a result, the commenter believes that we have no specific statutory authority to implement the surety bond requirement.

Response: While the commenter is correct that we did not finalize the January 20, 1998 proposed rule in the allotted amount of time as required by section 902 of the MMA, we did repropose the surety bond provisions in the August 1, 2007 proposed rule and have 3 years from that date to finalize the regulation as required by the MMA. Therefore, we believe that we are within our statutory authority for finalizing this rule.

Comment: Some commenters questioned the need for the surety bond requirement by noting that the surety bond requirement specified in the BBA of 1997 reflected a different era when there were fewer requirements to become a DMEPOS supplier. For example, one commenter observed that DMEPOS suppliers are now required to become accredited, and most are about to be subject to additional scrutiny and cost controls via the DMEPOS competitive bidding program. Another commenter stated that the NSC did not routinely perform onsite inspections before issuing billing numbers. Commenters stated the NSC is now required to perform an onsite inspection for every DMEPOS supplier that seeks to obtain a Medicare billing number.

Response: While these commenters are correct in that we have implemented significant programmatic changes—such as the routine performance of onsite visits—we note that the problems that led to the enactment of section 4312 of the BBA are still prevalent in the

DMEPOS industry now. Indeed, the Office of Inspector General (OIG) continues to identify questionable conduct in the DMEPOS arena, as reflected in its recent report entitled, “Los Angeles County Suppliers’ Compliance with Medicare Standards: Results from Unannounced Visits; OEI–09–07–00550.”

We further note that on July 15, 2008, the Congress enacted the MIPPA which delayed the implementation of the DMEPOS Competitive Bidding Program. This, in our view, enhances the importance of the implementation of the surety bond requirement; with the delay in competitive bidding, we need to utilize the remaining tools at our disposal to prevent fraudulent activity in the DMEPOS arena. The onsite audits of every DMEPOS supplier serves as an important tool in ensuring that the NSC grants billing privileges to legitimate suppliers.

C. Bond Amount

Comment: Several commenters disagreed with our proposal to increase the amount of the surety bond from \$50,000 to \$65,000 based on the Consumer Price Index (CPI). One commenter stated that the proposal is flawed because it is not based on risk to the Medicare program or Medicare reimbursement levels, and that the amount should be adjusted downward to reflect reduced Medicare reimbursement to DMEPOS suppliers (that is, commenters noted that Medicare reimbursement to many DMEPOS suppliers has decreased, remained the same, or only minimally increased since 1997.) In addition, several commenters believe that we should assess whether our proposal to increase the surety bond amount, which would raise the annual cost of the surety bond requirement from \$150 million to approximately \$198 million, would have any appreciable increase in benefit. Other commenters stated that nothing in the surety bond requirement set forth in section 1834(a)(16)(B) of the Act or its history indicates that Congress ever contemplated inflation adjustments, or that the surety bond amount should be higher than \$50,000.

Response: We disagree with these comments for the following reasons. First, section 4312(a)(16)(B) of the BBA states that the bond amount must be “in an amount that is not less than \$50,000.” The phrase “not less than” makes it clear that we have the authority to impose a bond amount higher than \$50,000. Second, nowhere in the statute or the legislative history did the Congress indicate that the bond amount should be tied to the reimbursement

levels of the provider or supplier type in question. To the contrary, we believe that the Congress intended for the key factor in determining the bond amount to be the risk of fraudulent activity posed by that class of provider or supplier.

Having said this, we nevertheless have elected to reduce the base surety bond amount from \$65,000 to \$50,000 for two reasons. First, we wish to preclude an additional regulatory impact associated with implementing section 4312(a) of the BBA. This is especially true with respect to small, rural DMEPOS suppliers, as discussed in section G of the Regulatory Impact Analysis. Second, we believe that \$50,000 is an appropriate starting point for the bond requirement. Using the statutory minimum amount will, in our view, allow us to better gauge whether a higher surety bond amount is needed to protect the Medicare Trust Funds.

However, we are establishing a surety bond amount higher than \$50,000 for those DMEPOS suppliers that pose a significantly higher risk to the Medicare program. In addition, we will evaluate the impact of this \$50,000 surety bond amount requirement for certain DMEPOS suppliers before considering any increase in the base surety bond amount.

Comment: Commenters stated there was no need to impose a tiered approach to determine what bond amount to impose on a DMEPOS supplier based on past conduct. For established DMEPOS suppliers, commenters believed that CMS and the OIG have significant administrative remedies to address misconduct, including excluding the supplier from the Medicare program. Commenters maintained that we should limit the bond requirement to new suppliers, which is consistent with the Congress' original intent under the BBA.

Response: We do not agree with the commenters that there is no need to establish elevated surety bond amounts for DMEPOS suppliers that pose additional risk to the Medicare program, nor do we agree with the commenters' statement that the Congress intended to limit the surety bond requirement to only new DMEPOS suppliers. As for the former comment, we believe that elevated bond amounts are necessary to protect the Medicare Trust Fund and Medicare beneficiaries. Furthermore, we note that section 4312(a) of the BBA expressly states that "the Secretary shall not provide for the issuance (or renewal) of a provider number * * *" unless the supplier furnishes a surety bond of not less than \$50,000. (Emphasis added.) Use of the term "renewal" evidences a

congressional intention to apply the surety bond requirement to those DMEPOS suppliers already in the Medicare program.

It is true that CMS and the OIG have various administrative remedies to address fraudulent or abusive conduct by DMEPOS suppliers after they have enrolled to participate in Medicare; however, we believe that the Congress intended to require that suppliers of DMEPOS meet financial solvency requirements and to ensure that Medicare could recoup some, if not all, of the improper payments made to suppliers of DMEPOS.

Comment: One commenter stated that the preamble to the August 1, 2007 proposed rule factually "misdescribes" the January 20, 1998 proposed rule. The commenter indicated that the January 20, 1998 proposed rule did not propose a \$65,000 surety bond level, but instead proposed a sliding scale approach starting at \$50,000 and rising to 15 percent of reimbursement.

Response: We agree that the January 20, 1998 proposed rule included a minimum \$50,000 surety bond amount. We note that the \$65,000 figure in the August 1, 2007 proposed rule has been reduced in this final rule to \$50,000, except in the case of high-risk suppliers. We consider any DMEPOS supplier with at least one adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment to be a "high-risk" supplier.

Comment: Several commenters maintained that we should have sought public comment on the reasonableness of increasing the surety bond amount from \$50,000 to \$65,000. The commenters stated that this change represents an increase of 25 percent over the original \$50,000 surety bond requirement proposed in the January 20, 1998 proposed rule.

Response: In the August 1, 2007 proposed rule, we solicited public comments on the amount of the surety bond for DMEPOS suppliers and, as already noted, we have chosen to reduce the minimum surety bond amount to \$50,000.

Comment: One commenter stated that, although we justified our proposal to increase the amount of the surety bond from \$50,000 to \$65,000 based on the CPI, expecting a DMEPOS supplier to obtain a surety bond that far exceeds the value of the supplier's annual claims seems unreasonable.

Response: As already discussed, neither section 4312(a) of the BBA nor its legislative history indicate that the Congress intended for the bond amount to be tied to the level of reimbursement

a supplier receives from the Medicare program. The regulatory impact section of the proposed rule (72 FR 42008) stated that, "We estimate that as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." While we are reducing the amount of the surety bond from \$65,000 to \$50,000, the lowest amount allowable under section 4312(a)(16)(B) of the BBA, and limiting its impact to certain DMEPOS suppliers, we understand that the implementation of this rule will require some DMEPOS suppliers to reconsider their participation in the Medicare program because of the added cost of the bond.

Comment: A commenter stated that the surety bond requirement may increase costs for small DMEPOS suppliers and reduce costs for large DMEPOS suppliers. The commenter stated that the January 20, 1998 proposed rule provided for a sliding scale approach to the bond requirement for DMEPOS suppliers in that the surety bond started at \$50,000 and rose to 15 percent of Medicare reimbursement (capped at \$3 million). Many commenters stated that a tiered system would be more equitable.

Response: We do not believe that establishing a sliding scale approach is appropriate because of the operational complexity associated with establishing and maintaining this approach. Moreover, it is important to note that 4312(a) of the BBA requires that we establish a surety bond in an amount of not less than \$50,000. Accordingly, by statute, the lowest amount that we can establish for a DMEPOS surety bond is \$50,000, and based on the public concerns about higher bond amounts, we have decided to implement higher surety bond amounts only for those individuals or organizations that pose a higher risk to the Medicare program.

Comment: A commenter stated that the financial soundness of DMEPOS suppliers will be a factor in the price of surety bonds. The commenter maintained that the financial soundness of a DMEPOS may result in DMEPOS suppliers not being able to obtain surety bonds. The commenter stated that this is one reason for keeping the amount of the surety bond low and for allowing sufficient time for a competitive market to be formed for surety bonds.

Response: We agree that financial soundness will be a key determinant in whether a DMEPOS supplier will be able to secure a surety bond and the

amount that the DMEPOS supplier will have to pay for the bond. To reduce cost associated with obtaining a bond, we have reduced the amount of surety bond from \$65,000 bond to \$50,000. In addition, we have delayed the implementation of this regulation.

Comment: One commenter maintained that we did not adequately outline the rationale for adjusting the amount of the surety bond in the August 1, 2007 proposed rule. The commenter noted that the inflation adjusted bond will be 25 percent higher than the \$50,000 bond originally contemplated by the Congress. The commenter stated that, since it appears that our only rationale for increasing the bond amount is based on the passage of time, imposing this additional financial and administrative burden on suppliers is arbitrary.

Response: We note that this final rule has been revised to reduce the proposed \$65,000 surety bond amount to \$50,000, the minimum allowable under the statute.

Comment: One commenter stated that the proposed surety bond amount of \$65,000 is realistic, and that establishing a bond requirement for the majority of DMEPOS suppliers is consistent with standard suretyship.

Response: We appreciate this comment. However, this final rule has been revised to require a \$50,000 surety bond (the minimum allowable under the statute) for certain DMEPOS suppliers.

D. Timeframe for Implementation

Comment: Several commenters requested that we give DMEPOS suppliers at least 120 days to comply with this final rule instead of 60 days following publication of this rule.

Response: We agree with the commenters and have revised § 424.57(d)(1) (proposed § 424.57(c)(26)) to require existing suppliers (that is, DMEPOS suppliers already enrolled in the Medicare as of the publication date of this final rule in the **Federal Register**) of DMEPOS to obtain a surety bond no later than 9 months after the effective date of this final rule. Moreover, beginning 120 days after the effective date of this final rule, DMEPOS suppliers, who are seeking to enroll in the Medicare program and are subject to the provisions of this final rule, are required to furnish to the NSC a surety bond of at least \$50,000 from an authorized surety for each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges. Accordingly, any DMEPOS supplier, except those specified in § 424.57(d)(15) (proposed § 424.57(c)(26)(ii)), seeking to enroll a

new practice location or to change the ownership of an existing DMEPOS supplier after the publication date of this rule is required to submit to the NSC a surety bond of at least \$50,000 beginning 120 days after the effective date of this final rule. The DMEPOS supplier must submit a surety bond of at least \$50,000 with its enrollment application on the date of filing.

Comment: Several commenters suggested that we delay implementing this final rule. The commenters stated that we should wait to see if our accreditation process reduces the level of Medicare fraud in the DMEPOS industry. Another commenter stated that we should consider granting a transition or “grace period” that gives suppliers an opportunity to, among other things, assess the availability of surety bonds and learn how to obtain surety bonds before requiring them to comply with any surety bond requirement. The commenter also urged us to grant this transition or “grace period” to allow time for a robust market for DMEPOS supplier surety bonds to develop.

Response: We agree with the commenters and we have delayed the requirement of a surety bond for certain existing DMEPOS suppliers until 9 months after the effective date of this final rule, and 120 days after the effective date of this final rule for certain new DMEPOS suppliers. These delays will give existing suppliers an opportunity to assess and determine whether they will continue to participate in the Medicare program during the accreditation implementation without incurring additional costs associated with a surety bond.

E. Definitions

Comment: Several commenters noted that § 424.57(a) of the August 1, 2007 proposed rule stated that paragraph (3) of the proposed definition of “unauthorized surety” means, among other things, a surety that “[f]ails to pay CMS in full the amount requested, up to the penal sum of the bond when presented with a request for payment within 30 days of written notification.” The commenters stated that there is no requirement that the request for payment be supported by sufficient evidence, and recommended that we revise paragraph (3) as follows: “Fails to pay CMS any amount owed, up to the penal sum of the bond, within 30 days of receipt of a request for payment and sufficient evidence to support the request.”

Response: We have removed the proposed definition of an “unauthorized surety” from this final rule.

Comment: One commenter stated that it is unclear whether there will be any ramifications if a DMEPOS supplier purchases a bond from a surety that becomes an “unauthorized surety.” The commenter believes that requiring the supplier to obtain a replacement bond without receiving a refund of the premium would penalize the wrong party.

Response: We believe it is essential that DMEPOS suppliers select surety bond companies that will honor their commitments to pay the bond amount when presented with sufficient evidence by CMS or the NSC that a debt is owed by the DMEPOS supplier.

Comment: One commenter suggested that we revise the definition of a “penal sum” from, “a sum to be paid (up to the value of the bond) by the surety as a penalty under the terms of the surety bond when a loss has occurred” to “a sum in the amount of the bond and the maximum obligation of the surety if a loss occurs.” The commenter stated that the penal sum is not a penalty to be paid; rather, it represents the surety’s obligation to pay what the principal owes up to the penal sum.

Another commenter suggested that we revise the definition of “sufficient evidence” from “means the documentation that CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of amounts due and payable under the statute and regulations” to “means documents CMS supplied to the surety that established both the amount of Medicare funds a DMEPOS supplier received in excess of amounts due and payable under applicable statutes and regulations and that this amount was an obligation of the surety.”

Response: In response to these comments, we have revised the definitions of “penal sum” and “sufficient evidence” in § 424.57(a).

Comment: A commenter stated that the definition of “chain suppliers of DMEPOS” should include chain pharmacies.

Response: We agree that publicly traded chain suppliers of DMEPOS include chain pharmacies as long as there are 25 or more distinct practice locations under common ownership.

Comment: One commenter stated that our definition of a “small supplier” is inconsistent and problematic. The commenter maintained that we made an arbitrary decision in the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule (April 10, 2007, 72 FR 17992) to define

a small supplier as a supplier that generates gross revenue of \$3.5 million or less in annual receipts, but did not discuss why it chose \$3.5 million as the ceiling as opposed to some other figure (for example, the commenter noted the SBA defines a small business as a business that has less than \$6.5 million in annual receipts). The commenter stated that we should adopt SBA's definition of a small business.

Response: During the development of the April 10, 2007 final rule (72 FR 17992), we adopted a \$3.5 million revenue or less standard for DMEPOS suppliers. This standard was developed in consultation with the SBA during the development of the DMEPOS competitive bidding final regulation. To ensure consistency with both the April 10, 2007 rule and the guidance furnished by the SBA, we will continue to define a small supplier as a supplier that generates gross revenue of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.

F. Payment and Liability

Comment: A commenter stated that proposed § 424.57(c)(26)(iii) indicates that we will revoke or deny a DMEPOS supplier's billing privileges based on submission of a bond that does not reflect the requirements of that section. The commenter stated that because, in its view, DMEPOS suppliers may experience difficulty obtaining surety bonds in the marketplace, we should recognize situations where DMEPOS suppliers have made a good faith effort to secure a surety bond that meets our requirements if the market will not provide such a product. The commenter suggested that we add language to proposed § 424.57(c)(26)(iii) that recognizes a DMEPOS supplier's good faith effort to obtain a surety bond that satisfies the surety bond requirement.

Response: We believe that the delay in the implementation of this final rule will allow a surety bond market to develop for prospective DMEPOS suppliers as well as existing DMEPOS suppliers enrolled in the Medicare program. Therefore, we are not revising § 424.57(d)(4) (proposed § 424.57(c)(26)(iii)).

Comment: One commenter stated that proposed § 424.57(c)(26)(iv)(C) appears to conflict with § 424.57(c)(26)(iv)(B). The commenter noted that § 424.57(c)(26)(iv)(C) states that "the surety remains liable for unpaid claims, CMPs, or assessments that * * * took place during the term of the bond or rider * * *," and § 424.57(c)(26)(iv)(B) states that "[t]he surety is liable for unpaid claims, CMPs, or assessments

that are presented to the surety for payment when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, CMPs, or assessment occurred * * *." (Emphasis added.) The commenter suggested revising § 424.57(c)(26)(iv)(B) to place liability on the surety whose bond was in effect at the time of each respective default as provided by § 424.57(c)(26)(iv)(C).

Response: We agree that the provisions discussed above are in conflict and have revised § 424.57(d)(5) in this final rule (proposed § 424.57(c)(26)(iv)) accordingly.

Comment: A commenter stated that we need to clearly spell out the process and timeframes by which we would request payment from the surety.

Response: We believe that the provisions of this final rule contain sufficient information on both the process and the timeframes involved in our payment requests.

Comment: A commenter stated that it is unclear whether the original application and documentation for approval of the surety bond should be submitted to the NSC or the U.S. Department of Health and Human Services (HHS). The commenter maintained that the surety bond, all riders, and notices of cancellation should be filed with HHS to avoid any confusion or loss of data should HHS change contractors.

Response: Since the NSC is our designated contractor responsible for establishing DMEPOS billing privileges, all documentation (for example, bond approval, riders, and notices of cancellation) associated with the surety bond should be sent to the NSC.

Comment: Several commenters maintained that a default on the surety bond should be based on a finding of wrongdoing, not merely on the existence of debt, which may be disputed and subject to the Medicare appeals process. The commenters stated that a surety's liability should be triggered only when there has been a final determination of an assessment for fraud or other misconduct against a DMEPOS supplier and the time to file an appeal has expired. Commenters also stated that there is no valid rationale to impose liability under the bond before a final determination has been made because the bond, by its terms, guarantees payment of the assessment. Another commenter stated that underwriters should not be required to reimburse CMS for any overpayment until the DMEPOS supplier exercises its Medicare appeal rights, supplier liability for the claim is firmly

established, and the supplier is past due on repayment.

Response: We do not agree that we should be prohibited from seeking payment from a surety until all supplier appeals have been exhausted. In addition, we believe that it is appropriate for the surety to pay CMS a total of up to the full penal amount of the bond when sufficient evidence is presented. We note that in revised § 424.57(d)(14), if a surety has paid CMS on the basis of liability incurred under a surety bond and to the extent the DMEPOS supplier that obtained the bond is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS refunds the DMEPOS supplier the amount the DMEPOS supplier paid to CMS to the extent that the amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

Comment: In order to limit the surety's liability to the penal sum of the bond, one commenter recommended that proposed § 424.57(c)(26)(iv) and any required surety bond form should include the following language: "Regardless of the number of years the bond is in force, the number of premiums paid, or the number of claims made, the surety's aggregate liability shall not be more than the penal sum stated above."

Response: We agree with this commenter and have revised § 424.57(d)(5) (proposed § 424.57(c)(26)(iv)) accordingly.

Comment: A commenter stated that permitting the surety to cancel the bond as to future events will protect CMS and the surety. The commenter stated that a bond is an essential requirement for participation in the DMEPOS program. The commenter stated that if the surety learns that a DMEPOS supplier is violating Medicare rules or receiving Medicare overpayments, then the surety should be able to cancel the bond. The commenter observed that the surety would remain liable for overpayments and other debts already incurred, but it could avoid watching its obligations increase if the DMEPOS supplier violates Medicare rules or receives Medicare overpayments. Since the bond would no longer be in effect, the commenter noted that the supplier would be ineligible for reimbursement for supplies furnished after the effective date of cancellation. In effect, the commenter believes that the surety's cancellation of the bond would protect CMS from having to continue to do

business with violators. The commenter stated that a right to cancel protects the Medicare program from fraud and abuse. The commenter noted that, if the surety mistakenly cancels a DMEPOS supplier's surety bond, then the supplier can simply obtain a replacement bond. The commenter recommended that proposed § 424.57(c)(26)(iv) and any required surety bond form should include the following language: "The Surety may terminate its liability for future acts of the Principal at any time by giving thirty (30) days written notice of termination of the bond of the Obligee."

Response: We agree with this commenter and have revised § 424.57(d)(6) (proposed § 424.57(c)(26)(v)) accordingly.

Comment: One commenter stated that the success of the surety bond requirement depends on the reasonableness of the terms of the surety bond. The commenter stated that sureties have to be able to, based on the merits of each applicant, provide the bonds to qualified DMEPOS suppliers and decline to offer bonds to unqualified DMEPOS suppliers. If the terms of the bond alone place an unreasonable risk on the surety, then the bonds will be available only to the largest, best-capitalized DMEPOS suppliers. Therefore, the commenter maintained that it is important that we carefully consider the bond terms and make sure that they conform to reasonable standards. First, the commenter stated that the penal sum of the bond has to be the limit of the surety's obligations. If the surety cannot be sure of its maximum exposure, it cannot underwrite the risk. Second, the commenter stated that the surety should be able to cancel the bond on 30 days advance notice. The commenter stated that the surety would remain liable for any overpayments or other defaults that occur before the effective date of the cancellation but would be able to prevent future losses. Finally, the commenter maintained that there must be a reasonable time limit on the surety's exposure so that at the end of that period, if no claims have been made, the surety can close its books on the bond and return any security or collateral the principal provided.

Response: We have revised the relevant provisions, including the provisions pertaining to 30-day cancellations, and believe we have addressed the commenter's concerns in this final rule.

Comment: A commenter stated that proposed § 424.57(c)(26)(iv)(B) and (C) partially address the time limit of the surety's liability. The commenter

indicated that subparagraph (B) provides that the bond in force when the claim is made is responsible. The commenter stated that this implies that the earlier bond in force when the events giving rise to the claim occurred is not responsible. The commenter stated that, in effect, any bond is discharged from liability (except for claims already made) once the supplier furnishes a new bond that complies with the surety bond requirement. The commenter also stated that if at any point the DMEPOS supplier fails to furnish an acceptable bond, then for up to 2 years we can make claims on the existing bond based on overpayments or other events that took place during the bond term. However, the commenter observed that subparagraph (C)(2) starts the 2-year period from the date the supplier failed to submit a required bond or the date the DMEPOS supplier's billing privileges were terminated, whichever is later. The commenter stated that, in theory, there should not be much difference between either starting dates since the supplier's billing privileges should be terminated as soon as it fails to renew or submit a bond. Sureties will be concerned that, despite CMS oversight, we may not promptly terminate the supplier's billing privileges. The commenter stated that the surety could then face a liability period longer than the anticipated 2-year timeframe solely because of the neglect of CMS or one of its contractors. The commenter also stated that this issue would greatly concern sureties. Therefore, the commenter recommended that we amend subparagraph (C)(2) to read as follows: "Were imposed or assessed by CMS or the OIG during the 2 years following the date the bond terminated, expired or was cancelled."

Response: We agree, and have revised subparagraph § 424.57(d)(5)(iii)(B) (proposed § 424.57(c)(26)(iv)(C)(2)) accordingly.

Comment: A commenter states that proposed § 424.57(c)(26)(v)(G) provides that "[t]he liability of the DMEPOS supplier and the surety to CMS is not extinguished by * * * [t]he DMEPOS supplier's failure to exercise available appeal rights under Medicare or to assign the rights to the surety." (Emphasis added.) The commenter stated that, upon receiving notification of a default from CMS or the NSC, the surety should be provided the same right to the appeals process as the principal because to provide otherwise would result in unjust enrichment for CMS.

Response: We disagree with the commenter because our relationship is

primarily with the DMEPOS supplier, as opposed to the surety. Accordingly, we believe that only the DMEPOS supplier should be afforded appeal rights.

Comment: A commenter noted that proposed § 424.57(c)(26)(viii)(B) states that DMEPOS suppliers must submit either a continuous bond or an annual bond to the NSC. The commenter stated that requiring a continuous surety bond would be the most efficient approach and would require minimal maintenance in terms of recordkeeping.

Response: We agree with this comment and have revised § 424.57(d)(4) (proposed § 424.57(c)(26)(viii)(B)) to require a continuous bond. We believe that a continuous bond contains administrative benefits for the surety, the DMEPOS supplier, and CMS.

Comment: One commenter asserted that proposed § 424.57(c)(26)(x) appears to conflict with proposed § 424.57(c)(26)(iv)(B). The commenter noted that § 424.57(c)(26)(iv)(B) states that "[t]he surety is liable for unpaid claims, CMPs, or assessments that are presented to the surety for payment when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, CMPs, or assessment occurred * * *" (Emphasis added.) Section 424.57(c)(26)(x), the commenter observed, indicates that "[i]f a DMEPOS supplier changes its surety during the term of the bond, the new surety will be responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond." (Emphasis added.) The commenter stated that the provision also indicates that "[t]he previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety." (Emphasis added.) The commenter suggested revising proposed § 424.57(c)(26)(iv)(B) to place liability on the surety whose bond was in effect at the time of each respective default as provided by proposed § 424.57(c)(26)(iv)(C), which states that "the surety remains liable for unpaid claims, CMPs, or assessments that * * * took place during the term of the bond or rider * * *"

Response: We agree and have revised the provisions of this final rule to ensure consistency.

Comment: A commenter stated that the surety bond requirement should cover only amounts of proven losses, and thus, should not include amounts for civil monetary penalties.

Response: We disagree because CMPs are debts owed to the Federal government.

G. Bond Cancellations and Lapses

Comment: Several commenters noted that proposed § 424.57(c)(26)(v) allows a DMEPOS supplier to terminate or cancel a surety bond upon proper notice to the NSC. The commenter maintained that the surety should also be allowed to terminate or cancel the bond. Another commenter agreed that it is important for the surety to be able to cancel the bond by providing advance written notice to the DMEPOS supplier, CMS, and the NSC. The commenter noted that the events listed in proposed subparagraphs (A) through (G) of § 424.57(c)(26)(v) do not extinguish any preexisting liability, but cancellation of the bond does prevent new liability from accruing. The commenter suggested that we revise the last sentence of the introductory text of paragraph (v), which immediately precedes subparagraphs (A) through (G), to read as follows: “The liability of the DMEPOS supplier and the surety to CMS arising out of the overpayments or other events that occurred prior to cancellation is not extinguished by any of the following * * *”

Response: While we believe that a surety has the right to cancel a bond and that it is purely a contractual matter between the two parties, we agree that a surety should notify the DMEPOS supplier and the NSC when a cancellation occurs. Therefore, we have revised § 424.57(d)(6) accordingly.

Comment: A commenter stated that we should not prohibit Medicare payments during any lapses in surety bond coverage as proposed in § 424.57(c)(26)(v). The commenter maintained that this prohibition would penalize suppliers by treating reimbursable Medicare payments during a lapse in surety bond coverage as overpayments. The commenter stated that this practice would, among other things, result in a windfall to the government. Another commenter stated that notice from CMS indicating that the surety bond is not in effect and that payments will cease in 30 days would be sufficient and fair. The commenter maintained that retroactively applying a denial is too great a penalty for “what could well be a simple administrative lapse.”

Response: We disagree with the commenter. If the bond coverage lapses, the supplier is immediately and automatically out of compliance with the requirement at § 424.57(d) (proposed § 424.57(c)(26)) that the bond coverage be maintained in order for the DMEPOS

supplier to receive payment from Medicare for its provision of DME.

Comment: A commenter noted that proposed § 424.57(c)(26)(v) requires a surety to immediately notify the NSC if there is a lapse in surety bond coverage. The commenter stated that this requirement is unreasonable because the surety with the expiring surety bond would not know whether the replacement surety bond has been issued or if the principal’s billing privileges have been revoked. The commenter believes that providing the surety with the right to cancel the bond and requiring the surety to notify CMS and NSC if the surety has received a notification of cancellation from the principal should be adequate.

Response: We agree with the commenter and have revised the language in § 424.57(d)(6)(iv) (proposed § 424.57(c)(26)(v)(D)) to read as follows: “The surety must immediately notify the NSC if there is a lapse in the surety’s coverage of the supplier.” The surety, in other words, will only be responsible for notifying the NSC if its coverage of the supplier has lapsed.

Comment: Several commenters believe that we should have provisions to protect a DMEPOS supplier if its surety bond is erroneously reported as lapsed or cancelled. The commenters stated that a DMEPOS supplier should have a reasonable, though limited, amount of time to prove that an error occurred, and that it has a valid surety bond.

Response: Section 424.57(e) (redesignated § 424.57(d)) specifies that a revocation of a DMEPOS supplier’s billing privileges does not become effective until 15 days after the date on the revocation notice letter. During that 15-day period, the supplier may submit a corrective action plan (CAP) as specified in § 424.535(a)(1).

Comment: A commenter stated that the last two sentences of proposed § 424.57(c)(26)(x) appear to contemplate that a bond will remain in force, but the surety would change. The commenter stated that this would be highly unlikely, even though it is arguably possible. The commenter stated that if a DMEPOS supplier wants to change sureties, then the typical way this would occur would be for it to execute a new bond with the new surety and substitute the new bond for the existing one. The commenter stated that the respective liabilities of the sureties would then be controlled by subparagraphs (B) and (C) in proposed § 424.57(c)(26)(iv). The commenter stated that if the DMEPOS supplier provides an acceptable bond from a different surety, then the new bond

should be liable for any claims made after its effective date “regardless of when the payment, overpayment or other event giving rise to the claim” occurred, and the replaced bond and its surety should have no further liability other than for claims already made. Therefore, the commenter suggested striking the last two sentences of proposed § 424.57(c)(26)(x).

Response: We agree and have revised § 424.57(d)(9) (proposed § 424.57(c)(26)(x)) by removing the last two sentences.

Comment: One commenter noted that proposed § 424.57(c)(26)(xii) would give CMS the ability to revoke a DMEPOS supplier’s billing privileges if the supplier fails to obtain, maintain, and timely file a surety bond. The commenter characterized this action as a penalty and stated that revoking a DMEPOS supplier’s billing privileges would be harsh. The commenter stated that revocation of billing privileges should be reserved for the most flagrantly noncompliant DMEPOS suppliers, that some DMEPOS suppliers may fail to comply with proposed § 424.57(c)(26)(xii) due to reasons outside of their control, and that first-time “simple negligence” should be addressed with a less punitive sanction.

Response: As stated previously, if the bond coverage lapses the supplier is immediately out of compliance. This provision is similar to the current requirement at § 424.57(c)(11) that a DMEPOS supplier maintain comprehensive liability insurance at all times.

H. Exceptions to the Bond Requirement

Comment: Several commenters urged us to establish an exception to the surety bond requirement for physicians and NPPs. The commenters stated, among other things, that the Congress did not intend for CMS to impose this requirement on physicians and NPPs; and referred to a conference report on the BBA of 1997 indicating that “the Conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals.” The commenters also noted that section 4312(c) of the BBA, which provides the Secretary with the authority to apply surety bond requirements to health care providers other than DME suppliers, explicitly states that the surety bond requirements may not be extended to physicians or other practitioners as defined in section 1842(b)(18)(C) of the Act. Commenters in support of an exception stated: (1) Physicians and NPPs are already licensed by the State; (2) large DMEPOS suppliers that generate significant

revenue may be able to absorb the cost of the surety bond more than a physician or NPP who occasionally furnishes DMEPOS items for the convenience of his or her patients; (3) government reports show that unscrupulous individuals and corporations, not physicians who primarily furnish DMEPOS only as an ancillary service to their patients, engage in fraudulent DMEPOS supplier conduct; (4) personal instruction in disease processes and prevention of injuries for most Medicare beneficiaries needs to come from a professionally trained clinician, not from a DMEPOS mail order catalogue; and (5) physicians who occasionally provide DMEPOS items for the convenience of his or her patients may choose not to renew their DMEPOS supplier numbers due to the costly burden of the surety bond requirement, and that this could impede the ability of Medicare beneficiaries to access immediate, safe, effective, and quality care.

Conversely, several commenters stated that physicians and NPPs should not be exempt from the surety bond requirement. One commenter stated that physicians have been implicated in large Medicare fraud prosecutions and that large, publicly-traded chain suppliers of DMEPOS have been at risk for bankruptcy. The commenter believed that requiring these suppliers to obtain a surety bond would provide an alternative means for CMS to recover overpayments. Another commenter stated that physicians are no less likely to cost the Federal program money than other DMEPOS suppliers, and a surety bond should not be difficult for them to obtain. Another commenter stated that we should not exempt physicians and NPPs that furnish DMEPOS as a convenience to their patients from the surety bond requirement unless they otherwise meet the criteria for an exception.

Response: In reviewing the statutory language and legislative history of section 4312(a) of the BBA, we believe that the Congress intended to create an exception for physicians and NPPs. Accordingly, we have revised this final rule to establish an exception to the surety bond requirement for physicians as defined in section 1861(r) of the Act and NPPs as defined in section 1842(b)(18) of the Act, provided that the items are furnished only to the physician or NPP's own patients as part of his or her professional service as defined at section 1861(q) of the Act and as described in section 1861(s)(2)(K) of the Act.

Comment: Several commenters recommended that we not require a

surety bond for accredited and State-licensed orthotic and prosthetic personnel. A commenter stated that State-licensed orthotic and prosthetic suppliers are highly clinical and service-oriented, and the training and expertise required to provide quality orthotic and prosthetic care differ greatly from the provision of DME, which typically requires little more than opening a store front and obtaining a Medicare supplier number.

Response: We agree with these commenters and have created an exception for State-licensed orthotic and prosthetic personnel operating in private practice and who are only providing custom-made orthotics and prosthetics and supplies related to custom-made orthotics and prosthetics.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed orthotic and prosthetic supplier operating in private practice who is only providing custom made orthotics and prosthetics and supplies related to custom made orthotics and prosthetics, and orthotic and prosthetic personnel employed by a medical supply company or co-owned with another individual or entity or furnishing DME. Since a medical supply company can enroll as a DMEPOS supplier with or without employing State-licensed orthotic and prosthetic personnel, we do not believe that medical supply companies employing State-licensed orthotic and prosthetic personnel qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the licensed orthotic or prosthetic personnel. Similarly, we believe orthotic or prosthetic personnel are not operating in private practice when another individual or entity is a part owner of the enrolled orthotic or prosthetic personnel's practice location. Specifically, the business must be solely-owned and operated by orthotic or prosthetic personnel who are making custom made orthotics or prosthetics.

Finally, as with physicians and NPPs, State-licensed orthotic and prosthetic personnel operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior, whereas a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Consequently, since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on

whether State-licensed orthotic or prosthetic personnel are accredited.

Comment: One commenter stated that DME suppliers and non-accredited suppliers of orthotic and prosthetic services that bill Medicare for orthotic and prosthetic services should be subject to the surety bond requirement. The commenter stated that, to the extent that these providers submit claims for orthotic and prosthetic care when they do not possess "independent validation" (for example, orthotic and prosthetic accreditation certification or State orthotic and prosthetic licensure), the surety bond requirement is one way for us to provide a basic level of protection to the Medicare program.

Response: We agree with this commenter. As such, we are not establishing an exception to the surety bond requirement for medical supply companies that employ orthotic or prosthetic personnel.

Comment: Some commenters urged us to exempt physical therapists, occupational therapists, and physician assistants (PAs) from the surety bond requirement. The commenters stated that physical therapists, for instance, who work in private practice often specialize in treating certain conditions and provide DMEPOS supplies that are integral to their plan of care. The commenters also maintained that, given the small size of physical therapy practices and the scope of services they furnish, the potential for fraud and abuse is limited. Commenters also stated that the cost of the surety bond may force some physical and occupational therapists to not enroll or to discontinue their enrollment as a DMEPOS supplier, which may hinder patient access to their services. Commenters also expressed concern that the surety bond requirement will allow unqualified DMEPOS suppliers—rather than qualified NPPs—to fabricate custom splints because of their ability to pay to obtain a surety bond. Commenters stated that the fabrication of custom orthotics and the frequent adjustments they entail cannot be performed by a DMEPOS supplier that is not treating the Medicare beneficiary. Yet another commenter stated that suppliers of material for splints will be affected by the surety bond requirement if occupational therapists that provide DMEPOS services opt out of the DMEPOS program.

In addition, commenters stated that the surety bond requirement will have a negative impact on physical and occupational therapists, certified hand therapists, and PAs that work for small businesses, not-for-profit organizations, and minority-owned companies. The

commenter stated that small businesses that provide occupational therapy services, such as outpatient occupational therapy clinics, are already burdened with the DMEPOS application and reoccurring certification requirement and accompanying expense.

Response: While PAs are included in the definition of “nonphysician practitioner” in accordance with section 1842(b)(18)(C) of the Act, physical therapists and occupational therapists are not included. However, we believe that physical therapists in private practice and occupational therapists in private practice should be exempt from the surety bond requirements, provided that the therapist furnishes orthotics, prosthetics and supplies to the therapist’s own patients as part of the physical or occupational therapy service.

We believe that this approach is consistent with both the provisions that had been established in the DMEPOS competitive bidding program prior to the enactment of the MIPPA, as well as the intention of section 4312(a) of the BBA. As with prosthetic and orthotic personnel, we believe that there is a clear distinction between a DMEPOS supplier enrolled as a physical or occupational therapist in private practice and physical or occupational therapists employed by a medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed physical or occupational therapists, we do not believe that medical supply companies employing State-licensed physical or occupational therapists qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the licensed physical or occupational therapist. In addition, we believe that a physical or occupational therapist is not operating in private practice when another individual or entity is a part owner of the enrolled therapist’s practice location. Specifically, the business must be solely-owned and operated by the physical or occupational therapist.

Finally, as with physicians and NPPs, and State-licensed orthotic and prosthetic personnel operating in private practice, physical and occupational therapists risk their State license if they are found guilty of fraudulent or abusive behavior. Nonphysician practitioners, physical therapists in private practice and occupational therapists in private

practice who furnish DMEPOS products or services that are not incident to a physician’s order, or who enroll to provide DMEPOS to the general public, must separately enroll and are subject to the bonding requirement. Finally, we recognize that although physical and occupational therapists, certified hand therapists, and PAs work for small businesses, not-for-profit organizations, and minority-owned companies, the bonding requirement is the responsibility of the owner(s) of the DMEPOS supplier, regardless of the size of the business.

Comment: A commenter stated that we should require DMEPOS suppliers that have a history of committing Medicare fraud and abuse to obtain a surety bond.

Response: We appreciate this comment and are establishing an increased surety bond amount for those DMEPOS suppliers that have significantly higher risk.

Comment: Some commenters asked us to waive the surety bond requirement for nursing facilities that provide DMEPOS services and bill Medicare for those services for their own residents. The commenters stated that the surety bond requirement aims to deter fraudulent conduct that is primarily and historically associated with small, independent, and commercial DMEPOS suppliers, not with nursing facilities that provide DMEPOS to their own residents. The commenters also stated that nursing facilities are subject to other legal and regulatory requirements that ensure that they are qualified to provide DMEPOS services to their residents. The commenters also stated that we did not demonstrate in the August 1, 2007 proposed rule that DMEPOS fraud in nursing homes is a bona fide problem.

Response: We disagree with the commenters and note that nothing in the statute or section 4312(a) of the BBA indicates a Congressional intent to exempt nursing facilities from the surety bond requirement. Indeed, the statute requires all suppliers of DME, except for physicians and NPPs who provide DME to their patients, to provide the Secretary with a surety bond.

Comment: Some commenters stated that we should develop an exception to the surety bond requirement for pharmacies that provide DMEPOS only when necessary for the administration of a drug and that furnish DMEPOS as a convenience to their patients. The commenters believe that requiring pharmacies to obtain a surety bond may prevent or discourage them from providing DMEPOS services to Medicare beneficiaries, who benefit

from being able to obtain all of their medications, including those that must be administered via a medical device, from a single pharmacy.

One commenter stated that we should exempt pharmacies that furnish home infusion DMEPOS services (in other words, services that require medications to be administered intravenously in a patient’s home) and pharmacies that provide a small volume of DMEPOS from the surety bond requirement unless they have had a prior adverse history.

Response: In reviewing the legislative history of section 4312(a) of the BBA and the overall purpose of the surety bond requirement, we do not believe that there was a congressional intention to exempt pharmacies—regardless of size or setting—from the surety bond requirement.

Comment: Several commenters stated that we should develop an exception to the surety bond requirement for large, publicly-traded chain DMEPOS suppliers. Some commenters stated that these companies are subject to laws such as the Sarbanes-Oxley Act, which targets corporate fraud by requiring public companies to implement internal controls, enhances financial disclosures, and imposes penalties for noncompliance. This indicates that large, publicly-traded companies are not the type of businesses that the Congress intended to target with the surety bond requirement. The commenters maintained that the Congress supported the surety bond requirement because it was concerned about “fly-by-night” companies that can quickly and inexpensively set up sham businesses to fraudulently receive Medicare reimbursement. Other commenters stated that large, publicly-traded companies tend to have established relationships with the Medicare program and significant assets. As a result, they pose less risk of nonpayment to the Medicare program than other DMEPOS suppliers, which may have less established relationships with the Medicare program and fewer assets.

One commenter suggested criteria that we could use to exempt large, publicly-traded chain suppliers of DMEPOS from the surety bond requirement. The commenter suggested that in order for a large, publicly traded DMEPOS supplier to be exempt from the surety bond requirement, we could require the DMEPOS supplier to have a minimum net worth for the chain (as set by CMS) and be publicly-traded. The commenter recommended that the supplier’s net worth should be \$5 million. The commenter also stated that we might

also consider the following factors: Prior history of paying Medicare debts; revocation or suspension of a license to provide health care products or services; Federal or State criminal convictions related to the delivery of health care products or services; and exclusion(s) from Federal or State health care programs. Yet, another commenter stated that we may wish to adopt criteria for what would constitute a "large, publicly-traded company," such as a dollar threshold for capitalization and annual gross sales volume.

Conversely, many commenters urged us not to establish an exception to the surety bond requirement for large, publicly-traded chain suppliers of DMEPOS. One commenter stated that the exception should not be granted because large, publicly-traded chain suppliers of DMEPOS represent the same level of risk for inappropriate Medicare billing as other DMEPOS suppliers. Another commenter stated that such high volume suppliers pose significant risk exposure, particularly if they become bankrupt. Yet another commenter stated that there is no legitimate basis to exempt larger DMEPOS suppliers from the surety bond requirement.

Response: In reviewing the statutory language and legislative history of section 4312(a) of the BBA and the overall purpose of the surety bond requirement, there is nothing to indicate that the Congress intended to exempt publicly-traded chain DMEPOS suppliers from the surety bond requirement. Accordingly, we are not able to establish such an exemption for publicly-traded chain DMEPOS suppliers.

Comment: Some commenters urged us to exempt all State-licensed chain pharmacies from the surety bond requirement without regard to whether they are "large" or "publicly-traded." Some commenters stated that, unlike other DMEPOS suppliers, community pharmacies are subject to numerous and rigorous Federal and State standards. Other commenters stated that staff pharmacists, technicians, and other employees at the community chain pharmacies have no financial incentive to engage in Medicare fraud because their compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items.

Response: While it may be true that staff pharmacists at pharmacies do not have an incentive to perpetuate schemes that may increase reimbursement levels for the pharmacy, there is nothing in section 4312(a) of the BBA or its legislative history to indicate that the Congress intended to exempt these

suppliers from the surety bond requirement. As such, we disagree that we should establish a broad based exception for all State-licensed chain pharmacies.

Comment: A commenter stated that there should be a monetary cap on the amount of the surety bond required for DMEPOS suppliers that belong to a chain. The commenter believed that this cap should not be limited only to publicly traded DMEPOS suppliers.

Response: We disagree that such a cap should be established, since DMEPOS suppliers are enrolled separately and are required to obtain a distinct NPI for each practice location if the DMEPOS supplier is operating as an organizational entity.

Comment: Several commenters stated that businesses falling under the Small Business Administration's (SBA) definition of "small business" should be exempt from the surety bond requirement.

Commenters stated that criteria for an exception to the surety bond requirement for small businesses could be based on a percentage of Medicare revenue and/or a percentage of revenue from Medicare DMEPOS.

Response: We disagree that we should establish an exception for small businesses based solely on the fact they are defined as a small business by the SBA. This would create an exception for nearly all DMEPOS suppliers and would effectively nullify the provisions contained in section 4312(a) of the BBA. Moreover, we believe that this requirement will limit the Medicare program's exposure to fraudulent DMEPOS activity; enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or our designated contractor to seek payments from a surety up to the penal sum; and help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers.

Comment: Several commenters stated that if we implement the surety bond requirement, it should hold all DMEPOS suppliers to the same standard and no exceptions to the requirement should be granted.

Response: We disagree with the commenters because, as previously explained in this final rule, the Congress intended for some categories of DMEPOS suppliers to be exempt from the surety bond requirement.

Comment: Several commenters stated that if a DMEPOS supplier is in "good standing" with Medicare or has operated for a number of years (for example, 5 years) without committing Medicare fraud or abuse, then we should exempt the supplier from the surety bond requirement. Other commenters stated that we should exempt from the surety bond requirement those DMEPOS suppliers that have no prior adverse history with Medicare. The commenters maintained that we should exempt from the surety bond requirement all DMEPOS suppliers that: (1) Have been enrolled in the DMEPOS program for at least 10 years; (2) have never had their Medicare billing privileges revoked; (3) pose no increased risk to the Medicare program; (4) have not engaged in materially questionable billing practices in the past; and (5) have never had any history of criminal, civil, or administrative sanctions imposed against them.

Response: We disagree with the commenters. We do not believe that anything in section 4312(a) of the BBA indicates that the Congress intended for us to establish such a broad based exception for DMEPOS suppliers participating in the Medicare program. In addition, we do not believe that a broad based exception would address systemic problems with fraud and abuse perpetuated by significant numbers of newly enrolling DMEPOS suppliers each year.

Comment: Several commenters maintained that established DMEPOS suppliers that open new locations or that acquire established DMEPOS suppliers should be exempt from the surety bond requirement. The commenters stated that the value of the surety bond in these instances would be small compared to the financial and administrative burden imposed on the DMEPOS suppliers.

Response: We disagree with the commenters. While we are establishing an exception to the surety bond requirement for certain DMEPOS suppliers, for reasons discussed in the preamble to this final rule we do not believe that it is appropriate to establish a broad based exception for new DMEPOS practice locations or changes of ownership for existing DMEPOS suppliers.

Comment: Many commenters stated that we should consider establishing an exception to the surety bond requirement for suppliers that provide DMEPOS services on an occasional basis or in a low volume. For example, one commenter stated that a DMEPOS supplier with annual payments of less than a specified dollar amount would be

exempt from the surety bond requirement.

Response: We disagree with the commenters. It is not possible for us to determine whether a newly enrolling DMEPOS supplier will only bill on an occasional basis or in low volumes on a prospective basis. In addition, we believe that newly enrolling DMEPOS suppliers should develop a business case and market analysis to determine whether it makes business sense to open and establish a new DMEPOS supplier business. Moreover, with the delay in implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, we believe that existing DMEPOS suppliers will need to make the business decision as to whether to participate in the Medicare program after the full implementation of accreditation in September 2009.

Comment: Several commenters stated that we should establish an exception to the surety bond requirement for home health agencies and hospices that provide DMEPOS items as a convenience to their patients. One commenter stated that in a 1999 report by the Government Accounting Office (GAO) entitled "Medicare Home Health Agencies: Role of Surety Bonds in Increasing Scrutiny and Reducing Overpayments," the GAO indicated that the primary benefit of a surety bond is the scrutiny a surety provides as it reviews an applicant. The commenter stated that the GAO recommended that home health agencies with a proven track record in returning overpayments be exempt from the surety bond requirement. The commenter also stated that we did not explain why we ignored this information in the August 1, 2007 proposed rule.

Response: While we are aware of this report, we do not believe that it is appropriate to establish an exception to the bonding requirement for home health agencies and hospices. To the extent that HHAs provide DME to their patients, the statute requires that they submit a surety bond to the Secretary. We also note that we continue to experience systemic problems with fraud and abuse perpetuated by significant numbers of home health agencies. To address this specific concern of home health fraud, we initiated a provider enrollment home health demonstration in FY 2008 in Harris County, Texas and in select counties in California. Based on the results of these demonstrations, we will consider expanding these demonstrations into other parts of the country.

Comment: Several commenters believe that we should exempt rural DMEPOS suppliers from the surety bond requirement. The commenters stated that exempting rural DMEPOS suppliers that are in good standing with Medicare and that do not otherwise pose a risk to the Medicare program (for example, meet our accreditation standards) will ensure appropriate access to DMEPOS items for rural beneficiaries.

Conversely, another commenter stated that we should not exempt rural DMEPOS suppliers from the surety bond requirement unless they otherwise meet the criteria for an exception.

Response: While we understand the commenter's concerns, we do not believe that it is appropriate to establish a broad-based exception for rural DMEPOS suppliers based solely on the fact that they are located in a rural area. As stated above, we believe that rural DMEPOS suppliers should only receive an exception if they meet other criteria for an exemption.

Comment: Several commenters believe that holding all suppliers to the same surety bond requirement would place a disproportionate burden on smaller suppliers, give an unfair advantage to larger suppliers that may have more financial resources, and would not appropriately safeguard the Medicare Trust Fund from fraud. The commenters stated that small DMEPOS suppliers, particularly those located in rural areas, may not be able to remain in business if they are subject to the surety bond requirement because the cost of the bond would exceed their annual Medicare reimbursement for DMEPOS items.

Response: As stated previously, we do not believe that it is appropriate to establish a broad-based exception for small or rural suppliers of DMEPOS unless they meet other criteria for an exception.

Comment: A commenter stated that the surety bond requirement will not stop fraud committed by pharmacies that furnish home infusion DMEPOS services or home infusion pharmacies because there will always be a means to fraudulently bill Medicare for services. However, the commenter maintained that the surety bond requirement will decrease the availability of DMEPOS services for patients that need home infusion DMEPOS services. Another commenter stated that we should not exempt from the surety bond requirement those pharmacies that provide DMEPOS as a convenience to their patients unless they otherwise meet the criteria for an exception.

Response: As stated above, the purpose of a surety bond is to: (1) Limit the Medicare program risk to fraudulent DME suppliers; (2) enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; (3) ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or our designated contractor to seek payments from a surety up to the penal sum; and (4) help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers. In addition, while we believe that some DMEPOS suppliers will make the decision to withdraw from the Medicare program due to the additional costs associated with the surety bond, we believe that Medicare beneficiaries will not encounter barriers to care.

Comment: One commenter stated that it is a community pharmacy that receives Medicare reimbursement for selling diabetic supplies to patients. The commenter indicated that it has neither rented any equipment nor bid on any Medicare contracts. If this final rule is implemented, the commenter asked whether it would be subject to the surety bond requirement.

Response: We are not adopting an exception to the surety bond requirement for community pharmacies because the requirement is designed to ensure that owners of community pharmacies maintain basic financial solvency requirements to continue participation in the Medicare program.

Comment: One commenter stated that nothing prevents us from creating exceptions to the surety bond requirement based on the reasonableness of the exceptions.

Response: We agree that the Secretary has the authority to establish exceptions to the surety bond requirement for, among other entities, providers of services and suppliers of orthotics, prosthetics, and supplies. In response to public comments, we have established several exceptions to the bonding requirement for certain suppliers of DMEPOS, specifically certain suppliers of orthotics, prosthetics, and supplies in this final rule.

Comment: One commenter recommended that we delay publishing this final rule until we receive explicit guidance from the Congress on the types of exemptions that should be provided to the surety bond requirement. The commenter stated that, since 10 years have passed since the BBA was enacted, there appears to be no particular sense

of urgency to publish this final rule. Another commenter stated that neither the BBA nor its accompanying conference report gives us the authority to grant surety bond exceptions for certain classes of suppliers. Several other commenters questioned the need for the surety bond requirement at all stating that the bond requirement specified in the BBA of 1997 reflected a different era. For example, one commenter observed that DMEPOS suppliers are now required to become accredited; another commenter stated that the NSC now performs on-site inspections before issuing billing numbers.

Response: We continue to believe that section 4312(a) of the BBA permits us to establish an exception to the final rule's surety bond requirement. Moreover, in developing this final rule, we have considered the impact that accreditation will have on the suppliers of DMEPOS.

Comment: Commenters recommended that we implement a risk-based system that would require only DMEPOS suppliers that are likely to submit inappropriate billings to Medicare to comply with the surety bond requirement. Specifically, commenters stated that the requirement should apply only to DMEPOS suppliers that—(1) Have no prior history with the Medicare program unless they are part of an existing large, publicly-traded Medicare-enrolled DMEPOS suppliers that is opening a new pharmacy or taking ownership of another pharmacy; (2) suppliers that have engaged in materially questionable billing practices in the past; and (3) suppliers that have had any history of criminal, civil, or administrative sanctions involving the Medicare program. One commenter believed that DMEPOS suppliers that fall into category 1 above should not be treated as new suppliers because they would be subject to the large DMEPOS supplier's policies and procedures. In addition, a commenter stated that, in determining the materiality of any billing practice under category 2 above, we should take into account the overall size of the DMEPOS supplier and its number of locations. Finally, a commenter stated that the surety bond requirement should only be applied based on the number of locations that might be involved in Medicare fraud and abuse unless there is evidence of corporate-wide efforts to engage in fraudulent activity.

Response: Consistent with section 4312(a) of the Balanced Budget Act of 1997 (BBA), this final rule implements section 1834(a)(16) of the Act by requiring certain Medicare suppliers of DMEPOS to furnish CMS with a surety

bond. In addition, by establishing an elevated surety bond for those DMEPOS with increased risk, we believe that we are implementing a risk-based system for those suppliers that are considered high-risk.

I. High-Risk Suppliers

Comment: One commenter disagreed with increasing the bond amount based on a supplier's elevated risk. The commenter maintained that additional risk is addressed by sureties in the underwriting process and that a surety evaluates whether to write a bond based on whether the surety believes the principal will perform its obligations. In addition, the commenter observed that high risk criteria are taken into account in the decision whether to write the bond and whether collateral is required from the principal.

Response: While we agree that sureties consider additional risk when determining whether to issue a bond, sureties may not know that a particular supplier poses additional risk to the Medicare program based on past practices. In order for Medicare to easily convey to the surety that a particular individual or organization poses an elevated risk level, we believe that it is appropriate for Medicare to require a higher surety bond amount for certain DMEPOS suppliers participating in the Medicare program or for those DMEPOS suppliers that may be seeking to re-enroll in the Medicare program. Accordingly, we believe that we are in a unique position to inform sureties that certain DMEPOS suppliers pose a higher-than-normal risk to the Medicare program.

Comment: One commenter stated that we should apply the surety bond requirement in a manner designed to exact the higher surety amount from DMEPOS suppliers that pose the greatest risk to the Medicare Trust Funds.

Response: We agree with the commenter that a higher surety amount should be required from DMEPOS suppliers that pose an elevated risk and have revised the provisions of this final rule accordingly.

Comment: A commenter recommended that we keep the initial surety bond to a single amount because CMS may need to gain some experience with implementing a base surety amount before it undertakes a more complicated approach that involves elevated amounts of surety bonds for higher risk DMEPOS suppliers.

Response: While we appreciate this commenter's recommendation, we do not believe that the implementation of varying surety bond amounts for high

risk suppliers will pose an undue administrative burden on CMS or our contractor, the NSC. In fact, no later than 120 days after the publication of this final rule, we will notify each existing DMEPOS supplier by mail of the need to obtain with an elevated bond to maintain its enrollment in the Medicare program. In addition, we will work with the NSC to conduct outreach to all DMEPOS suppliers regarding the need to obtain a surety bond. Our outreach efforts will include discussing the implementation of the surety bond rule during Open Door Forums, issuing listserv announcements from CMS and the NSC, and posting information regarding this new requirement on our Web site.

Comment: Several commenters stated that new DMEPOS suppliers that have no prior billing history with the Medicare program should be required to obtain a surety bond for 5 years to establish a pattern of compliance with Medicare rules and regulations. One commenter stated that, if no sanctions are imposed against these suppliers during this timeframe, then we should no longer require them to obtain a surety bond. The commenter stated that new DMEPOS suppliers should not include locations that are opened by DMEPOS suppliers that are exempt from the surety bond requirement.

Response: We disagree with the commenters because section 4312(a) of the BBA did not specify nor did we propose a limitation on the base bonding period. Accordingly, we are not adopting this recommendation to establish a minimum bonding period for existing or newly enrolling suppliers of DMEPOS. Nevertheless, we believe that the duration of the elevated surety bond amount should be limited. Accordingly, in this final rule, we have established a 3-year duration on elevated surety bond amounts. We believe that this affords the appropriate protections to the Medicare program, establishes a reasonable period of time for submission of an elevated surety bond amount, and is consistent with our established reenrollment period for DMEPOS suppliers found in § 424.57(f) (redesignated § 424.57(e)).

Comment: A commenter stated that, in general, surety bonds should be required for an entire category of licensees rather than exempting certain lower risk licensees. The commenter stated that requiring a bond from only a small segment of the group because that segment represents a higher risk and will likely cause future losses is a selection against the surety. According to the commenter, this is called adverse selection. The commenter stated that a

surety needs to underwrite the entire group in order to adequately price and spread the risk of exposure. The commenter stressed that adverse selection would discourage sureties from participating in a market and would make obtaining the bond more difficult for those subject to the surety bond requirement.

Response: While this final rule establishes exceptions for certain suppliers of DMEPOS, we believe that a sufficiently large number of other types of DMEPOS suppliers will remain in order for sureties to calculate and adjust for any adverse selection.

Comment: A commenter stated that many DMEPOS suppliers have "billing-related problems" with CMS, and that the vague proposed criteria (see 72 FR 42005) is not useful. The commenter believed that it would be difficult, if not impossible, for DMEPOS suppliers to obtain a bond from any surety if this type of criteria is used. The commenter recommended that only an "unpaid final action" that is not satisfied at the time a DMEPOS supplier applies for a surety bond be used to identify a DMEPOS supplier that would be subject to an elevated surety bond.

Response: We have clarified § 424.57(d)(4) (proposed § 424.57(c)(26)(iii)) to address this concern.

Comment: A commenter suggested that the surety bond requirement be eliminated after a business has had satisfactory relations with CMS for a 3-year time period. The commenter stated that this should apply to any surety bond. If CMS cannot adopt this recommendation due to a statutory restriction, then the commenter suggested that we reduce the bond level by \$10,000 for each successful year of relationship with CMS until the bond level amount reaches a minimum threshold of \$10,000. The commenter stated that this amount would then be in effect "until there is a problem of some kind."

Response: We do not have the statutory authority to lower the surety bond amount below \$50,000 and, as stated previously, section 4312(a) of the BBA did not specify nor did we propose a limitation on the base bonding period. Accordingly, we are not adopting this recommendation to establish a minimum bonding period for existing or newly enrolling suppliers of DMEPOS.

Comment: A number of commenters stated that we should require current Medicare-enrolled DMEPOS suppliers with a prior "adverse history" of criminal, civil, or administrative sanctions for billing-related problems to obtain a surety bond.

Response: We appreciate the commenters' support for surety bonds for those suppliers of DMEPOS that pose a significantly higher risk to the Medicare program and note that the provisions of this final rule cover such individuals.

Comment: One commenter observed that, according to the August 1, 2007 proposed rule, examples of final adverse actions include, but are not limited to, the following: Federal and State criminal convictions; formal or official actions such as a revocation of Medicare billing privileges; a revocation or suspension of a license; and an exclusion from participation in Federal or State health care programs. The commenter stated that our proposal to increase the bond amount by \$65,000 per occurrence if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds may penalize legitimate DMEPOS suppliers. The commenter stated that if the final rule imposes a surety bond requirement based on risk categories, then we need to create an exception to address honest mistakes by a DMEPOS supplier or the NSC. The commenter stated that we should limit such elevated costs to higher risk DMEPOS suppliers.

Another commenter stated that we need to specifically define the term "adverse actions." The commenter noted that even legitimate DMEPOS suppliers can be subject to overpayments, Federal investigation, or corporate integrity agreements. The commenter explained that, on their face, these actions could appear to be "adverse actions." To ensure that legitimate DMEPOS suppliers are not unfairly penalized by the surety bond requirement, the commenter maintained that we must list all "adverse actions" that would subject a supplier to elevated bond payments.

Response: We agree and have clarified what constitutes a final adverse action in § 424.57(c)(26)(a). A final adverse action means one or more of the following actions:

- (i) A Medicare-imposed revocation of any Medicare billing privileges;
- (ii) Suspension or revocation of a license to provide health care by any State licensing authority;
- (iii) Revocation or suspension by an accreditation organization;
- (iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(A)(i)) within the 10 years preceding enrollment, revalidation, or re-enrollment; or
- (v) An exclusion or debarment from participation in a Federal or State health care program.

Under the final adverse action as specified in section 221(g)(1)(A) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA), we believe that a final adverse action occurs when the action is imposed, not when a DMEPOS supplier has exhausted all of its appeal rights associated with the final adverse action.

In addition, we believe that the provider enrollment appeals process affords existing suppliers of DMEPOS with an administrative avenue to challenge a revocation determination.

J. Access to Bonds

Comment: A commenter stated that our surety bond requirement may hinder DMEPOS suppliers' ability to obtain surety bonds. The commenter indicated that sureties may be unwilling to provide surety bonds to DMEPOS suppliers because the surety bond requirement imposes conditions that extend beyond the standards in the surety bond industry. The commenter stated that we failed in the August 1, 2007 proposed rule to discuss how this final rule will directly affect the surety industry as well as DMEPOS suppliers' ability to obtain surety bonds. The commenter urged us to provide this type of analysis in the final rule.

Response: We believe that we have clarified the obligations of sureties in this final rule. Moreover, based on information received from sureties as well as our independent research, we are confident that legitimate DMEPOS suppliers will be able to acquire a surety bond.

Comment: A commenter maintained that there must be real-time access to supplier information for sureties to evaluate risks. If this information is not available or is not provided to sureties, then the commenter believed that surety bonds may not be available for DMEPOS suppliers.

Response: We agree that sureties will require appropriate financial information in order to evaluate the risks associated with issuing a bond to a particular DMEPOS supplier, and believe that a surety should ensure that the supplier furnishes this information to it.

Comment: One commenter stated that we must meet with surety bond underwriters and vet surety bond requirements with the underwriters to ensure underwriter participation, and then make any necessary changes to the surety bond requirement prior to implementing this final rule.

Response: We have examined the role of underwriters in this process and have

made revisions to this final rule as necessary.

Comment: A commenter stated that it is uncertain as to whether the surety industry will be willing to issue surety bonds that comport with the surety bond requirement. The commenter stated that it contacted three sureties. Two of the sureties stated that they would not issue such bonds. The other surety stated that it might consider issuing such bonds to DMEPOS suppliers with established and unblemished records of participation in the DMEPOS program. The sureties stated that they would not issue bonds to DMEPOS suppliers that have their billing privileges revoked.

Response: While we appreciate the commenter's concerns, we believe that a reasonable number of sureties will offer to issue bonds to DMEPOS suppliers. Indeed, we believe that our implementation of this requirement will help create a market for sureties, as will the delay in the implementation of the bond requirement.

Comment: A commenter recalled that in the past we have experienced difficulty in attempting to implement a surety bond requirement in the home health industry, and that we abandoned that proposal as unworkable. The commenter believes that we would have difficulty implementing a surety bond requirement in the DMEPOS industry and speculated that it would be difficult to identify companies that would issue surety bonds for the DMEPOS industry.

Response: As stated above, we are confident that significant numbers of sureties will offer to issue bonds to DMEPOS suppliers; however, we have delayed the implementation for existing DMEPOS suppliers until 9 months after the effective date of this final rule.

K. Standard Bond Form

Comment: One commenter stated that, instead of leaving the actual terms of the bond up to each supplier or surety, we should require each DMEPOS supplier and surety use a standard bond form. Otherwise, the commenter stated, CMS will have to review each bond form submission to verify that it meets the terms of the surety bond requirement. The commenter stated that this proposal would make it easier for DMEPOS suppliers to obtain the surety bond, remove any uncertainty as to whether a particular bond complies with the surety bond requirement, and relieve CMS of a large volume of work reviewing the terms of each bond submission.

Response: While we appreciate the commenter's suggestion, we believe that this final rule will provide DMEPOS

suppliers with the guidance and flexibility necessary to obtain surety bonds that meet the requirements of the final rule.

L. Suggested Alternatives

Comment: Several commenters proposed alternatives to the surety bond requirement. One commenter stated that financial statements have been recently used by CMS to determine the financial stability of DMEPOS suppliers that apply for competitive bidding. The commenter indicated that these statements should be an acceptable alternative to a surety bond. Another commenter observed that we could require a bank letter of credit from a DMEPOS supplier or a DMEPOS supplier could provide us with a letter from an insurance broker that verifies the supplier's worth.

Response: We disagree with the comments that the alternatives proposed would offer as much protection to the Medicare Trust Funds as the proposed surety bond. Also, none of the alternatives offered above would allow Medicare to recoup any mistaken payments.

Comment: One commenter stated that large DMEPOS chain suppliers could be given the option to buy a \$50,000 surety bond for each site or to buy one surety bond that equals 5 percent of their total reimbursement at all of their sites.

Response: We do not believe it is appropriate to allow chain stores to purchase a single bond that equals 5 percent of their total reimbursement. Moreover and as already stated, there is nothing in section 4312(a) or its legislative history to indicate that the Congress intended for the bond amount to be tied to the supplier's level of reimbursement.

Comment: One commenter stated that instead of implementing this final rule, we should exclude from the Medicare program DMEPOS suppliers that have been investigated by law enforcement (for example, the Federal Bureau of Investigation) and that have repaid millions of dollars in restitution to the government.

Response: While we have the authority to revoke the billing privileges of a DMEPOS supplier, we do not have the authority to exclude a DMEPOS supplier from the Medicare program. This authority rests with the OIG.

Comment: Some commenters stated that instead of implementing this final rule, we should make accreditation mandatory for all Medicare DMEPOS suppliers. One commenter stated that mandatory accreditation would ensure that DMEPOS suppliers are legitimate before they are issued billing numbers

and allowed to bill the Medicare program. Another commenter stated that mandatory accreditation would be more effective at reducing Medicare fraud than this final rule.

Response: We believe that accreditation will improve the quality of products and services furnished to Medicare beneficiaries, accreditation does not offer as much protection to the Medicare Trust Fund as the proposed surety bond; accreditation does not allow Medicare to recoup any mistaken payments. In addition, section 154(b) of the MIPPA added a new subparagraph (F). This subparagraph states that eligible professionals and other persons (defined above) are exempt from meeting the October 1, 2009 accreditation deadline unless we determine that the quality standards are specifically designed to apply to such professionals and persons.

Comment: One commenter stated that DMEPOS suppliers should be recredentialed on an annual basis, whereby suppliers would be required to provide year-end financial statements, current information, and insurance renewals.

Response: We disagree with this commenter that an annual recredentialed process is necessary and whether an annual recredentialed process would afford the Medicare program with the type of protection afforded by implementing a surety bond.

Comment: Another commenter stated that we should either delay further expansion of the competitive bidding program or allow provisions so that bidders who have submitted bids before the implementation of the surety bond requirement may have their prices adjusted accordingly when the surety bond requirement is implemented.

Response: As previously stated in this final rule, on July 15, 2008 the Congress enacted the MIPPA delaying the implementation of the DMEPOS Competitive Bidding Program.

Comment: One commenter stated the following: "Collecting on a surety bond should involve adequate due process protections for a surety. While that process can start with a letter from CMS[,] the surety should have the ability to 'look behind the curtain' to be sure that the recoupment has not already been accomplished before sending in the bond funds. The same process should apply in reverse. If CMS recoups after asking the surety for funds[,] then the burden should be on CMS to automatically refund the payment to the source of the funds, [which would be] the surety."

Response: We disagree with the commenter. Since our primary relationship is with the DMEPOS supplier, we believe that only the DMEPOS supplier is eligible to appeal our decision.

Comment: One commenter stated that we are attempting through the surety bond requirement to encourage Medicare beneficiaries who need diabetes testing supplies to purchase these supplies through mail order instead of from retail pharmacy DMEPOS suppliers. The commenter stated that this could potentially further reduce declining revenues that retail pharmacies would receive from selling Medicare DMEPOS. The commenter also stated that, although it would like to continue to provide beneficiaries with access to DMEPOS, the increasing number of requirements that we impose on DMEPOS suppliers, coupled with a potential decrease in retail-based revenues, could cause it to reassess the economic feasibility of being a DMEPOS supplier.

Response: We are implementing statutory requirements to establish a surety bond requirement for DMEPOS suppliers. We are not attempting to steer Medicare beneficiaries to any particular individual DMEPOS supplier or type of DMEPOS supplier (for example, mail order).

Comment: A commenter stated that the general tone of the August 1, 2007 proposed rule shows that we do not understand the complexity of the surety bond market. The commenter predicted that, if DMEPOS suppliers are required to obtain a surety bond as a result of this final rule, most of them will have a difficult time obtaining one. The commenter noted that many DMEPOS suppliers will have to undergo a grueling application process and that many of the suppliers will be denied a surety bond by sureties. The commenter observed that there will be difficulty with accounting records, lack of audited statements, lack of liquidity, and general lack of financial ability. Therefore, the commenter stated that any bond requirements should be slowly phased-in, be as automated as possible, and that bond forms be carefully vetted and discussed with the surety industry before publication by CMS.

Response: While we believe that some DMEPOS suppliers will not be able to obtain surety bonds because they have not maintained accounting records, or lack audited financial statements, liquidity, or financial ability to repay obligations, we do not believe that most legitimate and financially secure suppliers will find it difficult to comply with the standards necessary to apply

for and meet a surety's bonding requirements. In addition, as mentioned previously, we are delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule.

Comment: Several commenters stated that basic principles of administrative law require agencies to publish the factual basis for their proposed actions to encourage meaningful comments and argued that we have not provided any data requiring all DMEPOS suppliers to post a bond. Of particular relevance, according to the commenters, would be data to show the prevalence and demographics of suppliers that default on their Medicare debts inasmuch as the proposed rule would require suppliers to post a financial guarantee bond securing unpaid claims.

Response: We believe that the proposed rule was authorized by section 4312(a) of the BBA and published in accordance with the Administrative Procedures Act.

Comment: A commenter stated that it is not within the scope of this final rule to interfere with the private contractual rights of the surety and a DMEPOS supplier. The commenter observed that the terms of their contract are both negotiable and private, that due process in private insurance contracts is regulated at the State level, and that the parties to those contracts can take care of themselves.

Response: We agree that the specific language of a surety bond is not within the purview of this final rule. However, we believe that the Act grants us the authority to require DMEPOS suppliers to obtain a surety bond that satisfies certain minimum requirements as a prerequisite for participation in the Medicare program.

Comment: One commenter stated that we should not "bootstrap" the Federal surety approval list as the only source for surety bonds under the DMEPOS program. The commenter stated that the surety bond rule should allow for other less traditional bonding methods. The commenter noted that new surety bond providers need to emerge, which will take time. The commenter also stated that we should specify a system for approving new surety systems, which should adapt to the DMEPOS market and the risks of that market. According to the commenter, only by developing a number of surety bond providers and a competitive market will the DMEPOS program have a chance of keeping costs for surety bonds reasonable for suppliers.

Response: We disagree with this commenter because the use of the

Federal surety approval list will best ensure that sureties are legitimate firms. A link to this list, which is maintained by the Financial Management Service of the Department of the Treasury, will be posted on our Web site within 90 days after the publication date of this final rule.

Comment: One commenter stated that we gave commenters only 60 days to absorb and comment on the August 1, 2007 proposed rule, which consists of more than 60 pages. The commenter stated that this is unfair and will result in many people being unable to submit meaningful comments.

Response: The Administrative Procedures Act requires a 60-day comment period on proposed rules with a major impact. Therefore, we believe commenters were given adequate time to submit meaningful comments.

Comment: One commenter observed that in the August 1, 2007 proposed rule we indicated that we could conduct education and outreach efforts to help Medicare beneficiaries locate a replacement DMEPOS supplier if a significant number of DMEPOS suppliers leave the DMEPOS program as a result of the surety bond requirement.

Response: As stated above, by delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, and establishing exemptions for certain DMEPOS suppliers, CMS and the industry will have time to educate the public about their DMEPOS supplier alternatives.

M. Miscellaneous Comments

Comment: Some commenters stated that preexisting regulations (for example, the accreditation and liability insurance regulations) could be modified to prevent fraud in the program, rather than subjecting the DMEPOS industry to the surety bond requirement.

Response: We believe the comments are outside the scope of this final rule.

Comment: One commenter urged us to implement long-overdue regulations that would impose payment edits on practitioners and suppliers of orthotic and prosthetic care so that only qualified orthotic and prosthetic suppliers can be reimbursed under the Medicare program. The commenter stated that even though statutory directives require us to issue regulations within 1 year of enactment, we have never issued the regulations associated with section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA), a law

that limits payment of certain custom fabricated orthotics and all prosthetics to qualified practitioners and suppliers.

Response: We believe this comment is outside the scope of this final rule.

Comment: In order to more effectively protect Medicare beneficiaries and safeguard the Medicare Trust Fund, one commenter urged us to permanently expel DMEPOS suppliers that commit substantive fraud from the DMEPOS program.

Response: We do not have the statutory authority to permanently expel DMEPOS suppliers that commit substantive fraud from the DMEPOS program. This authority rests with the OIG. However, we are continuing to implement activities designed to protect the Medicare Trust Fund, including expanding onsite reviews of DMEPOS suppliers and revoking the billing privileges of DMEPOS suppliers that no longer meet the enrollment criteria found in § 424.57 and § 424.500 through § 424.555.

Comment: One commenter asked us to eliminate his copayment for DMEPOS items. He indicated that he is a diabetic and has a limited budget. He also stated that it is unfair that he must pay for his DMEPOS items when Medicare was paying for his DMEPOS items less than a year ago.

Response: While we understand this concern, we believe this comment is outside the scope of this final rule.

Comment: One commenter stated that, because we do not require home health agencies to obtain a surety bond, we should not require DMEPOS suppliers to obtain a surety bond.

Response: We believe this comment is outside the scope of this final rule.

Comment: The commenter maintained that if we enforced our own publication, Transmittal 656, and implemented existing laws, there would be no need to institute a surety bond requirement for orthotic and prosthetic suppliers.

Response: We believe this comment is outside the scope of this final rule.

Comment: A commenter found it difficult to believe that we cannot easily verify the legitimacy of home infusion services provided by pharmacies by crosschecking documentation (for example, medical procedures billed for services allegedly rendered to Medicare beneficiaries) in “the Medicare system.”

Response: While we appreciate this comment, we believe that this comment is outside the scope of this final rule.

Comment: Another commenter asked whether CMS realizes the impact the shortsighted implementation of Part D has had on independent pharmacies. The commenter stated that we refused

to acknowledge home infusion as a highly specialized service and “lumped” it with Part D.

Response: We believe this comment is outside the scope of this final rule.

Comment: Some commenters stated that we can reduce the risk of DMEPOS fraud and abuse by conducting credit checks on DMEPOS suppliers through established credit rating services, which can provide inexpensive and detailed credit reports on individuals and corporations. One commenter stated that we could require each supplier to provide evidence satisfactory to us that the supplier has a credit rating that will enable the supplier to pay 5 or 10 percent of its annual billings to Medicare if the supplier is not allowed to remain enrolled in the Medicare program.

Response: While we appreciate this suggestion, we believe it is outside the scope of this final rule.

Comment: Commenters stated that other measures, such as “real time” auditing and closely monitoring new DMEPOS suppliers, would more effectively deter fraud and abuse than the surety bond requirement.

Response: We believe this comment is outside the scope of this final rule.

Comment: One commenter stated that we underestimated the extent to which added DMEPOS costs will force independent pharmacists from the program, thus severely limiting patient access to DMEPOS and other medications. The commenter stated that it surveyed independent pharmacies after we issued the May 10, 2007 final rule (72 FR 17992), and that the survey targeted 10 Metropolitan Statistical Areas that were likely to be chosen to initiate our accreditation and competitive bidding program. The commenter reported that only 31 percent of independent pharmacists who responded to the survey indicated that they intended to submit bids to attempt to continue to sell DMEPOS supplies.

Response: We believe this comment is outside the scope of this final rule.

IV. Provisions of the Final Regulations

Based on public comments, we are adopting the provisions of the proposed rule with the following revisions:

In § 424.57(a), we are revising the definitions of “penal sum” and “sufficient evidence.” Based on public comments, we are adopting a change in the definition of the term, penal sum from “is a sum to be paid (up to the value of the bond) by the surety as a penalty under the terms of the surety bond when a loss has occurred.” to “is the amount of the bond and the

maximum obligation of the surety if a loss occurs.” We are also adopting a change in the definition of the term, sufficient evidence from “means the documentation that CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of amounts due and payable under the statute and regulations” to “means documents CMS may supply to the surety that—(1) Establish both the amount of Medicare funds a DMEPOS supplier received in excess of amounts due, the amount of the CMP or the amount of some other assessment against the DMEPOS supplier; (2) is payable under applicable statutes and regulations; and (3) was an obligation of the surety.” We believe that these revisions will clarify the terms throughout the regulation and ensure that sureties understand the financial obligation that they are incurring when they issue a surety bond to a DMEPOS supplier.

We believe that the following technical changes to § 424.57(c)(26) will improve the clarity of the surety bond requirements:

- Redesignating existing § 424.57(d) and (e) as § 424.57(e) and (f).
- Redesignating the provisions of proposed § 424.57(c)(26) as § 424.57(d).
- Revising § 424.57(c)(26) to state “must meet the surety bond requirement in paragraph (d) of this section.”
- Making cross-reference changes in the definition of DMEPOS supplier § 424.57(a) and the newly redesignated § 424.57(e).

In the introductory text of § 424.57(d) (proposed § 424.57(c)(26)), we are revising this provision to reflect the \$50,000 surety bond amount and the delay in implementation: “Except as provided in paragraph (d)(15) of this section and no later than 9 months after the effective date of this final rule, each DMEPOS supplier that is a Medicare-enrolled DMEPOS supplier for each assigned NPI to which Medicare has granted billing privileges (DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS after the effective date of this final rule are required to furnish to the NSC a surety bond of at least \$50,000 from an authorized surety for each assigned NPI for which the DMEPOS supplier is seeking to obtain billing privileges Medicare after 120 days following the effective date of this final rule.)

In § 424.57(d)(2) (proposed § 424.57(c)(26)(i)), we are clarifying the minimum requirements for a DMEPOS supplier. We specify that, unless a DMEPOS supplier meets the requirements for an exception in § 424.57(d)(15), the enrolling Medicare

DMEPOS supplier or the Medicare-enrolled DMEPOS supplier must obtain a surety bond for each National Provider Identifier (NPI) from an authorized surety. The surety bond must be in the amount prescribed by the NSC and in the form specified by the Secretary. We proposed to adjust the amount of the surety bond in the August 1, 2007 proposed rule from \$50,000 in 1997 by the CPI and calculate a higher surety bond amount to \$65,000. For reasons already stated, we have elected to require a base surety amount of \$50,000 for all individual and organizational suppliers of DMEPOS who do not meet the requirements for an exception in § 424.57(d)(15).

In § 424.57(d)(2)(i) (proposed § 424.57(c)(26)(i)(A)), we require a DMEPOS supplier to submit a surety bond with its initial paper or electronic Medicare enrollment application (CMS-855S, OMB Number 0938-0685), or with its paper or electronic revalidation, or reenrollment application. In addition, we are clarifying that for the purpose of meeting the surety bond requirement, a change of ownership constitutes an initial application and that suppliers of DMEPOS, except those with an exception in § 424.57(d)(15) (proposed § 424.57(c)(26)(ii)), are required to submit a surety bond in the amount prescribed by the NSC when a change of ownership occurs on or after the effective date of this final rule.

In § 424.57(d)(2)(iii) (proposed § 424.57(c)(26)(i)(C)), we are clarifying that we require a DMEPOS supplier seeking to enroll a new location to obtain a new surety bond for this new location since the location is also required to be enumerated with a unique NPI, unless the DMEPOS supplier is a sole proprietorship. With the implementation of the NPI as the standard health care identifier on May 23, 2008, we believe that the NPI, not the TIN, provides the best measure of program risk for the Medicare program. Moreover, we maintain that a DMEPOS supplier can obtain one TIN for many practice locations. However, these same DMEPOS suppliers can only obtain a single NPI per practice location (note that there is an exception for sole proprietorship). Accordingly, we are adopting a position that a separate surety bond be required for each NPI obtained for DMEPOS billing purposes. This will allow CMS, the NSC, and law enforcement an easy method to identify ownership, determine whether adverse legal actions have been previously imposed, and determine the value of the bond that each DMEPOS supplier must obtain and maintain in order to participate in the Medicare program.

Since each of these factors can enhance the overall risk to the Medicare Trust Fund, we have determined that the NPI, rather than the TIN, is more closely tied to the level of enrollment risk, and thus should be used in lieu of the TIN.

In § 424.57(d)(15) (proposed § 457.57(c)(26)(ii)), we are creating an exception to the bond requirement for a DMEPOS supplier operated by a Federal, State, local, or tribal government agency if the DME supplier has provided CMS with a comparable surety bond required under State law.

In the proposed rule, we stated that in order to satisfy this exception, a supplier must not have any unpaid claims, civil money penalties (CMPs), or assessments. We decided to remove this requirement from the final rule because we believe that the agency has adequate protection related to the financial status of government-operated DMEPOS supplier. Moreover, we want all of the exceptions to the surety bond requirement to be consistent for all supplier types.

As already discussed in section III of this final rule, we are also creating an exception to the bond requirement for physicians and NPPs, as defined in section 1842(b)(18)(C) of the Act provided that the items are furnished only to the physician or NPP's own patients as part of his or her professional service. We believe that requiring physicians and NPPs to obtain a surety bond for items furnished for patients other than the practitioner's own patients is appropriate and consistent with the provisions previously established in accreditation and the legislative history of section 4312(a) of the BBA. Nonphysician practitioners listed in section 1842(b)(18)(C) of the Act include the following: PAs, NPs, clinical nurse specialists, certified nurse anesthetists, certified clinical social workers, clinical psychologists, and registered dietitian or nutrition professionals.

We maintain that physicians and NPPs furnishing DMEPOS to someone other than the physician or NPP's own patients as part of his or her physician service are providing services as a medical supply company. Accordingly, we believe that physicians, including clinics and group practices, must obtain a surety bond if they are providing any DMEPOS items to someone other than the physician or NPP's own patient. This will ensure that physicians and NPPs meet the same quality and program safeguard standards as other DMEPOS suppliers who are not exempt from the bonding requirements found in § 424.57(d).

While it is true that the statutory exception identified in section 1834(a)(16) of the Act for physicians and NPPs does not specifically delineate between physicians and NPPs who provide DMEPOS supplies to their own patients and those who furnish such supplies in a different setting, we believe that there is a clear distinction between these two scenarios in terms of what the Congress intended in enacting section 1834(a)(16) of the Act. A physician or NPP who, for instance, furnishes DMEPOS supplies as part of her ownership of a DMEPOS supply company is not acting in her capacity as a practitioner who is providing ongoing care to a patient whom she is treating. Rather, the practitioner is operating his or her own side business. We do not believe that the Congress intended to allow a DMEPOS supply company to circumvent the surety bond requirement by hiring or contracting with a physician or NPP who can furnish DMEPOS supplies to the company's customers. To permit such a practice would be entirely inconsistent with the intent and spirit of section 1834(a)(16) of the Act. To ensure that this final rule conforms to the Congress's wishes, we have therefore limited the physician and NPP exception to those practitioners who furnish DMEPOS supplies only to their own patients.

We are also creating an exception to the bond requirement for State-licensed orthotic and prosthetic personnel operating in private practice and who furnish only orthotics, prosthetics, and supplies. Orthotic and prosthetic personnel are not operating in private practice when another individual or entity is a part owner of the enrolled practice location.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed orthotic and prosthetic personnel operating in private practice and operating independently of a medical supply company or other DMEPOS supplier and orthotic and prosthetic personnel employed by medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed orthotic and prosthetic personnel, we do not believe that medical supply companies employing State-licensed orthotic and prosthetic personnel qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the State-licensed orthotic or prosthetic personnel. Similarly, we believe

orthotic or prosthetic personnel are not operating independently when other individual or entity is a part owner of an enrolled DMEPOS supplier's practice location. Finally, as with physicians and NPPs, State-licensed orthotic and prosthetic personnel operating as a sole owner and operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior; whereas, a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Finally, since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on whether State-licensed orthotic or prosthetic personnel are accredited.

As already discussed in section III of this final rule, we are also creating an exception to the bond requirement for State-licensed physical and occupational therapist operating in private practice provided that the therapist furnishes only orthotics, prosthetics and supplies and only to the therapist's own patients as part of the physical or occupational therapy service. State-licensed physical and occupational therapist are not operating in private practice when another individual or entity is a part owner of the enrolled practice location. Moreover, a State-licensed physical and occupational therapist furnishing DMEPOS to someone other than the therapist's own patients as part of the physical or occupational therapy service is not exempt from the surety bond requirement.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed physical and occupational therapist operating in private practice and operating independently of a medical supply company or other DMEPOS supplier and a State-licensed physical and occupational therapist employed by a medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed physical and occupational therapists, we do not believe that medical supply companies employing State-licensed physical and occupational therapists qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the State-licensed physical and occupational therapists. Similarly, we believe State-licensed physical and occupational therapists are not

operating independently when another individual or entity is a part owner of an enrolled DMEPOS supplier's practice location. Finally, as with physicians and NPPs, State-licensed physical and occupational therapists operating as a sole owner and operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior; whereas, a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on whether State-licensed physical and occupational therapists are accredited.

In § 424.57(d)(4)(ii) (proposed § 424.57(c)(26)(iii)(B)), we require that DMEPOS suppliers obtain a surety bond of more than \$50,000 if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds by establishing elevated amounts of surety bonds for higher risk DMEPOS suppliers. We are establishing elevated amounts of the surety bond at a rate of \$50,000 per occurrence when a DMEPOS supplier, has an adverse legal action. The term "adverse legal action" is defined in § 424.57 and means a Medicare-imposed revocation of any Medicare billing number; suspension of a license to provide health care by any State licensing authority; revocation or suspension of accreditation; a conviction of a Federal or State felony offense within the last 10 years preceding enrollment, revalidation, or re-enrollment; or an exclusion or debarment from participation in a Federal or State health care program.

We maintain that these adverse legal actions create a significantly higher level of risk to the Medicare Trust Fund. Moreover, these adverse legal actions are consistent with the denial and revocation reasons found in § 424.530 and § 424.535, respectively.

The following is an example of how high-risk criteria would be used to increase the bond amount by \$50,000 per occurrence. A DMEPOS supplier would be required to obtain a surety bond in the amount of \$100,000, an increase of \$50,000 from the base surety bond amount of \$50,000, if the DMEPOS supplier or any of its owners, authorized officials, or delegated officials (as the terms "owner," "authorized official," and "delegated official," are defined in § 424.502) had their Medicare billing privileges revoked within the 10 years preceding enrollment, revalidation, or reenrollment. If the DMEPOS supplier or any of its owners, authorized

officials, delegated officials had more than one revocation in the last 10 years, then the amount of the surety bond the DMEPOS supplier would be required to obtain would increase \$50,000 per occurrence. Thus, a DMEPOS supplier with three different revocations during the preceding 10 years would be required to obtain a surety bond in the amount of \$200,000; \$50,000 for the base surety amount and \$150,000 (3 × \$50,000) for the multiple revocations. We are also establishing a provision to require DMEPOS suppliers that have a significantly higher level of risk to maintain a higher surety bond amount for 3 years.

As explained earlier, we believe that a final adverse action, as specified in section 221(g)(1)(A) of the HIPAA, occurs when the action is imposed, not when a DMEPOS supplier has exhausted all of its appeal rights associated with the final adverse action.

In § 424.57(d)(5) (proposed § 424.57(c)(26)(iv)), we specify additional DMEPOS supplier bond requirements and the surety's liability under the bond for unpaid claims, CMPs, or assessments up to a total of the full penal amount of the bond. Regardless of the number of years the bond is in force, the number of premiums paid, or the number of claims made, the surety's aggregate liability shall not be more than the penal sum stated above. Thus, for instance, we proposed that surety bonds be issued in an amount equal to \$50,000; and the surety is liable to us for up to \$50,000.

In § 424.57(d)(6) (proposed § 424.57(c)(26)(v)), we are revising this provision to include that the surety may terminate its liability for future acts of the principal at any time by giving 30 days written notice of termination of the bond of the obligee. Also, a supplier or surety may not place any limitations on the surety bond that contradict or nullify the requirements for a surety bond specifically provided for in this section. Any attempt to do so may result in revocation of the DMEPOS supplier's billing privileges and a determination that the surety is an unauthorized surety.

In § 424.57(d)(4) (proposed § 424.57(c)(26)(viii)(B)), we are revising this provision to specify that the type of bond required to be submitted by a DMEPOS supplier under this subpart is a continuous bond. While we are not defining the term, "continuous", we believe that the term, "continuous" means that the surety bond will renew automatically from year to year unless the bond is cancelled by surety or the DMEPOS supplier or the DMEPOS supplier fails to pay the premium.

In § 424.57(d)(15) (proposed § 424.57(c)(26)(ix)), we specify the circumstances under which a supplier will no longer be exempt from the surety bond requirement and must submit a surety NSC within 60 days after it receives notice that it no longer meets the criteria for an exception. Specifically, we maintain that a government-operated supplier that ceases to be operated by a government does not qualify for an exception must submit a surety bond; a physician or NPP who provides DMEPOS to beneficiaries other than his or her own patients; State-licensed orthotic or prosthetic personnel in private practice or physical or occupational therapists in private practice have their State license suspended or revoked; or otherwise no longer qualify for the exceptions described in paragraph (d).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the following issues pertaining to the information collection requirements discussed in this final rule.

Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Numbers (§ 424.57)

Section 424.57(d) outlines the surety bond requirements for DMEPOS suppliers. Specifically, § 424.57(d) states that each Medicare-enrolled DMEPOS supplier must obtain and furnish to the National Supplier Clearinghouse (NSC) a surety bond in the amount of \$50,000. The bond must be obtained from an authorized surety, and must be submitted for each NPI

obtained by a Medicare enrolled DMEPOS supplier.

Section 424.57(d)(2) outlines the minimum requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier. Section 424.57(d)(2)(i) (proposed § 424.57(c)(26)(i)(A)) requires a DMEPOS supplier that seeks to become a Medicare-enrolled supplier, to make a change in ownership, or to respond to a revalidation or reenrollment request to submit a surety bond of \$50,000 with its paper or electronic Medicare enrollment application (Form CMS-855S). Section 424.57(d)(2)(ii) (proposed § 424.57(c)(26)(i)(B)) states that a DMEPOS supplier seeking to become an enrolled supplier through the purchase or transfer of assets must provide a surety bond that is effective from the date of the purchase or transfer in order to exercise billing privileges as of that date. If the bond is effective at a later date, the effective date of the new DMEPOS supplier number will be effective no sooner than the effective date of the surety bond as validated by the NSC.

Section 424.57(d)(2)(iii) (proposed § 424.57(c)(26)(i)(C)) requires a DMEPOS supplier that is seeking to enroll a new location under a TIN for which it already has a DMEPOS surety bond in place to either obtain a new surety bond or to submit an amendment or rider to the existing surety bond.

Section 424.57(d)(4)(ii) (proposed § 424.57(c)(26)(iii)(B)) states that in addition to obtaining and maintaining a base surety bond in the amount of \$50,000, a DMEPOS supplier must also obtain and maintain an elevated surety bond in the amount prescribed by the NSC.

For those aforementioned requirements that are not already approved under OMB control number 0938-0685, we estimate the burden associated with the requirements in § 424.57(d)(2)(proposed § 424.57(c)(26)(i) and (iii)) to be 3 hours per DMEPOS supplier. In addition, we estimate that approximately 67,723 DMEPOS suppliers will comply with these requirements. Therefore, the estimated total annual burden is 203,169 hours.

Section 424.57(d)(6) (proposed § 424.57(c)(26)(v)) also states that a surety bond may be cancelled with written notice from the DMEPOS supplier to the NSC. The burden associated with this requirement is the time and effort necessary for either DMEPOS supplier to draft and submit the notice of cancellation to the NSC. We estimate the burden associated with this requirement to be 3 hours. In

addition, we anticipate that 250 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 750 hours.

Section 424.57(d)(15)(ii) (proposed § 424.57(c)(26)(ix)) requires a DMEPOS supplier, other than physicians and NPPs, as defined in section 1842(b)(18)(C) of the Act, that no longer qualifies for an exception under this final rule to submit a surety bond to the NSC within 60 days of receiving notice that it no longer qualifies for an exception. The burden associated with this requirement is the time and effort necessary for the DMEPOS supplier to obtain and submit a surety bond to the NSC within 60 days of receiving notice that it no longer qualifies for an exception. We estimate the burden associated with this requirement to be 3 hours. In addition, we anticipate that 100 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 300 hours.

Section 424.57(d)(9) (proposed § 424.57(c)(26)(x)) requires a DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond to submit the new surety bond to the NSC within 30 days of expiration of the previous bond. The burden associated with this requirement is the time and effort necessary to obtain and submit the new surety bond to the NSC. We estimate the burden associated with this requirement to be 3 hours. In addition, we anticipate that 250 suppliers will comply with this requirement. We estimate the total annual burden to be 750 hours.

Section 424.57(d)(12) (proposed § 424.57(c)(26)(xiii)) states that CMS may at any time require a DMEPOS supplier to show compliance with the requirements associated with 42 CFR part 424. The burden for this requirement is the time and effort associated with maintaining the necessary documentation on file. While this requirement is subject to the PRA, we believe the burden is exempt as stated in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

However, the burden associated with producing the documents upon request from CMS is estimated to be 30 minutes per DMEPOS supplier. We estimate that 500 DMEPOS suppliers will be asked to submit the requested documentation. The total annual burden associated with this requirement is estimated to be 250 hours.

The following is a summary of the comments received on the collection of information section and our responses.

Comment: A commenter stated that the suggested burden in the August 1, 2007 proposed rule for DMEPOS suppliers to obtain and keep a surety bond is too low in terms of hours and dollars. The commenter stated that obtaining all the information and attachments in an effort to obtain a bond will more than likely require 2 to 4 hours per application. The commenter also noted that a DMEPOS supplier may have to submit many applications in order to secure a surety bond, that it may have to deal with bankers and accountants to obtain the bond, and that it may have to borrow money in order to pay for the bond.

Response: We appreciate this comment and have revised our Collection of Information estimates accordingly.

Comment: A commenter stated that the surety bond requirement will

increase DMEPOS suppliers' cost and paperwork burden without accomplishing the Congress's and our goals. The commenter stated that sureties issuing financial guarantee bonds would be more likely to review a DMEPOS supplier's books and might request audited financial statements. Since most small suppliers do not have audited financial statements, the commenter stated that this requirement could pose a serious hurdle to their compliance. In addition, the commenter maintained that sureties would be more likely to ask for collateral to secure the issuance of a financial guarantee bond, and that sureties would likely favor highly liquid collateral such as letters of credit, which would require suppliers to incur an additional expense. Many commenters believe that this type of review is sensible when it is applied to DMEPOS suppliers that are new to the Medicare program, but not to established DMEPOS suppliers.

Response: We appreciate the concerns of the commenters, but continue to believe that surety bonds will serve as an effective deterrent to fraud and abuse, as well as provide the Medicare program with recourse when a supplier fails to pay claims against it, CMPs, or assessments.

Comment: A commenter stated that the cost and burden of the surety bond requirement will have a disproportionate impact on small DMEPOS suppliers. To ensure that small DMEPOS suppliers participate in the DMEPOS program if this final rule is implemented, the commenter stated that we should work with the SBA to extend low or no interest loans to qualified small DMEPOS suppliers for the express purpose of obtaining a surety bond.

Response: We do not have the authority to issue these types of loans to those DMEPOS suppliers that qualify as small businesses.

TABLE 2—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OCN	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden hours
§ 424.57(d)(2)(i)	0938–New ...	2,000	2,000	3.0	6,000
§ 424.57(d)(2)(ii)	0938–New ...	65,723	65,723	3.0	197,169
§ 424.57(d)(6)	0938–New ...	250	250	3.0	750
§ 424.57(d)(9)	0938–New ...	250	250	3.0	750
§ 424.57(d)(12)	0938–New ...	500	500	0.5	250
§ 424.57(d)(15)(ii)	0938–New ...	100	100	3.0	300
Total					205,219

We submitted a copy of this final rule to the OMB for its review of the information collection requirements. These information collection requirements are not effective until approved by OMB.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

The August 1, 2007 proposed rule was classified as economically significant, as the estimated annual cost of the surety bond requirement at that time was \$198 million. This was based largely on a preliminary estimation that 99,000 DMEPOS suppliers would need to obtain a surety bond in the amount of \$65,000, at an annual cost of \$2,000. As explained below, the establishment of a number of exceptions to the surety bond requirement, the reduction in both the bond amount and its cost, and the utilization of more current data in this final rule, has reduced the projected annual cost of the surety bond requirement from \$198 million to \$102.3 million. Accordingly, this final

rule is considered economically significant.

The RFA requires agencies to analyze the economic impacts of the regulation and alternatives for the regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year.

The RFA requires that a Regulatory Flexibility Analysis be conducted for all regulations that will have a “significant economic impact on a substantial number of small entities.” As already explained, we believe that the principal economic impact of this rule will fall on large, publicly traded chain pharmacies. Such organizations may have to expend several hundred thousand dollars to obtain surety bonds for each of their locations. However, even if we were to assume that each individual location—

if considered as a stand-alone business—qualifies as a small entity, we do not believe that the annual cost of a surety bond (\$1,500) would have an economic impact on it that rises to the level of qualifying as “significant.” The RFA generally defines “significant” as several percent; we do not believe that a \$1,500 cost would constitute more than one percent of a chain pharmacy location’s annual revenues. From that perspective, we do not believe that a Regulatory Flexibility Analysis is required.

We recognize that the cost of a surety bond may impact smaller pharmacies, such as single-site community pharmacies, as well as small medical supply companies in rural areas to a greater extent than large chain pharmacies. Though we do not believe that, at least in the case of community pharmacies, the bond requirement will have a significant economic impact on such businesses, we have elected to prepare a voluntary Final Regulatory Flexibility Analysis. As many of the requirements of the RFA are also contained in our Regulatory Impact Analysis, this Regulatory Impact Analysis section, taken together with the remainder of the preamble, constitutes the Final Regulatory Flexibility Analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing a rural impact statement since we have determined, and certify, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Our research has disclosed that well under 1 percent of a typical small rural hospital’s total annual reimbursement from Medicare would come from its enrollment as a DMEPOS supplier. Equipment furnished in hospitals is generally paid for as part of the facility’s direct or ancillary costs, rather than in the hospital’s capacity as a DMEPOS supplier. This is buttressed by the fact that less than four-tenths of one percent of all DMEPOS suppliers are hospitals.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates

require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold is currently \$130 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments, in the aggregate, or on the private sector, of \$130 million or greater; as previously mentioned, we estimate that the maximum annual cost of this final rule will be \$102.3 million. Accordingly, we are furnishing the aforementioned assessment in this final rule.

Executive Order 13132 established certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this rule under the threshold criteria of Executive Order 13132 and have determined that it does not significantly affect the rights, roles, and responsibilities of States.

The following is a summary of the comments received on the proposed rule’s regulatory impact analysis and our responses.

Comment: Some commenters stated that the surety bond requirement would mandate each Medicare-enrolled DMEPOS supplier to obtain a surety bond for each National Provider Identifier (NPI) the supplier holds, and that, under the provisions of the August 1, 2007 proposed rule, this requirement would be applied to all DMEPOS suppliers to the same extent. Commenters maintained that large, publicly traded DMEPOS chain suppliers and community pharmacies have numerous locations and NPIs. As a result, commenters stated that our surety bond requirement is not only over-inclusive but also unnecessary and unduly burdensome on these types of suppliers. Some commenters describe this requirement as punitive. To ensure that large, publicly traded chain DMEPOS suppliers are not unduly burdened, another commenter urged us to consider establishing a maximum or cap on the aggregate dollar amount of the surety bonds required for these high volume suppliers. Yet another commenter maintained that, if we do not establish an exception to the surety bond regulation for large, publicly traded companies that provide DMEPOS services, then we should allow a company with multiple locations that provide DMEPOS services to obtain one surety bond. The commenters stated that requiring this type of company to obtain multiple bonds is redundant and greatly increases the cost of doing business with the Medicare program.

Response: As previously stated, we are not establishing an exception to the surety bond requirement for publicly traded chain DMEPOS suppliers or community pharmacies, for there is nothing in section 4312(a) of the BBA or its legislative history that evidences a congressional intent to do so. Moreover, we disagree with the comment that we should not establish the surety bond at the NPI level, since the NPI is established by practice location for all DMEPOS suppliers except for those operating as a sole proprietorship.

Comment: One commenter stated that one way to equalize the burden on large DMEPOS suppliers is to require them to pay us a specified amount in lieu of a surety bond. The commenter stated that the amount could be the average cost of the bond for the previous year. The commenter called this option a “bond waiver fee.” The commenter believes that this approach would, among other things, keep unnecessary funds from going to sureties rather than taxpayers.

Response: We do not have the statutory authority to establish a bond waiver fee.

Comment: Several commenters stated that the surety bond requirement could have a devastating impact on Medicare beneficiaries needing these DMEPOS supplies. The commenters urged us to ensure that beneficiary access to DMEPOS services is not jeopardized as a result of the potentially large number of DMEPOS suppliers that may not enroll or discontinue their enrollment due to the financial burden the surety bond requirement may impose.

Response: We believe that the exceptions established in this final rule will help ensure that beneficiary access to DMEPOS supplies continues unabated. In addition, while we expect some DMEPOS suppliers to exit the Medicare program due to the surety bond requirement, we expect that other suppliers will enter the Medicare program as suppliers become acquainted with the new accreditation and surety bond requirements.

Comment: One commenter stated that many small towns have only a few DMEPOS suppliers, and that a number of those suppliers will not find obtaining a surety bond economical.

Response: We understand the potential impact that this final rule may have on small DMEPOS suppliers and have revised the regulatory impact accordingly.

Comment: One commenter stated that our assumption that most, if not all, of the Medicare business conducted by DMEPOS suppliers that withdraw from the DMEPOS program due to this final rule would be assumed by other

DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web) is flawed. The commenter stated that, if DMEPOS suppliers in the power mobility industry withdraw from the DMEPOS program as a result of this final rule, the assumption that mail order DMEPOS suppliers would assume their Medicare business would be inappropriate. The commenter stated that DMEPOS suppliers in the power mobility industry are required to conduct an in-home assessment, which would make Internet or nationwide mail order DMEPOS suppliers a nonviable substitute for DMEPOS suppliers in the power mobility industry. Other commenters maintained that we should not assume that these suppliers can satisfactorily meet the needs of all Medicare beneficiaries.

Response: If DMEPOS suppliers of a particular type of DMEPOS indeed exit the Medicare program upon implementation of this final rule, we believe that the remaining DMEPOS suppliers would offer the products and services similar to those of the exiting DMEPOS suppliers. As stated above, by delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, and establishing exemptions for certain DMEPOS suppliers, we believe that remaining DMEPOS suppliers will adjust to meet an increased demand for products and services.

Comment: One commenter stated that the surety bond requirement would unfairly penalize home health or home infusion companies that provide DMEPOS. The commenter questioned why the surety bond requirement would extend to these companies since the commenter maintains that CMS has stated that “the problem is not with home infusion providers.”

Response: We disagree with this commenter because the intent of a surety bond is, among other goals, to make sure that all DMEPOS suppliers meet more stringent financial requirements before being permitted to participate in the Medicare program.

Comment: A commenter noted that we stated in the August 1, 2007 proposed rule that the surety bond requirement could cause approximately 15,000 DMEPOS suppliers to decide to cease providing items to Medicare beneficiaries. However, the commenter believes that this figure is likely underestimated.

Response: We have revised the regulatory impact to account for the changes incorporated into this final rule.

Comment: Some commenters stated that we need to improve the regulatory impact analysis from the August 1, 2007 proposed rule. The commenters stated that the August 1, 2007 proposed rule violates Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Commenters also maintained, among other things, that we did not design the proposed rule in the most cost effective manner to achieve the regulatory objective, and that the regulation failed to take into account the cost of cumulative regulations, such as the accreditation process for DMEPOS suppliers, and its impact on patient care.

Response: While we disagree that the regulatory impact analysis in the proposed rule was in violation of Executive Order 12866, we have revised the regulatory impact analysis to address the concerns expressed.

Comment: Several commenters stated that we did not provide an analysis of the percentage of the industry that is contributing to Medicare fraud. Commenters also indicated that we overlooked many of the Regulatory Flexibility Act (RFA) requirements because we failed to address obvious alternatives that would minimize any significant impact of the proposed rule on small entities, including discussion of significant alternatives, such as an exemption from coverage of the rule, or any part thereof, for these small entities. The commenters stated that it is not clear from the RFA whether we intended for information in the regulatory impact analysis to serve as an initial regulatory flexibility analysis for the purposes of the RFA. Commenters indicated that our intent should be made clear in this final rule.

Response: We have revised the regulatory impact analysis to address the concerns expressed.

Comment: Several commenters believed that our economic analysis is incomplete. Specifically, although we provided information on the number of small DMEPOS suppliers that would likely be impacted by the surety bond requirement, commenters observed that our regulatory impact analysis offers little analysis of how the rule will economically impact small DMEPOS suppliers. For example, commenters noted that the analysis does not provide any information on the cost of complying with the surety bond

requirement based on the size of the DMEPOS supplier.

Response: We have revised our economic analysis to address the concerns expressed.

Comment: One commenter stated that the August 1, 2007 proposed rule fails to conform to the Office of Management and Budget’s (OMB) standards for analyzing regulations, which are set forth in OMB Circular A–4. The commenter observed that OMB Circular A–4 indicates that a regulatory impact analysis should analyze a manageable number of alternatives, including different enforcement methods and different degrees of stringency. According to the commenter, the proposed rule does not present this type of analysis, and the “Alternatives Considered” section in the preamble under “Regulatory Impact Analysis” neither presents nor analyzes any alternatives whatsoever.

Response: We disagree with the commenter that the proposed rule does not comply with OMB Circular A–4. Nevertheless, as already stated, we have revised the impact analysis based on comments we received in response to the August 1, 2007 proposed rule.

Comment: One commenter believes that the cost/benefit analysis of the August 1, 2007 proposed rule appears heavily weighted on the cost side. The commenter stated that the August 1, 2007 proposed rule estimates that 1,000 suppliers would be asked for bond documentation. If all of these suppliers required payment to Medicare from the surety, this amounts only to \$65,000,000 even though suppliers are being asked to potentially pay almost \$200,000,000 per year.

Response: As previously stated, we have reviewed and revised our regulatory impact analysis in this final rule to address matters such as those raised by the commenter.

Comment: A commenter stated that the August 1, 2007 proposed rule provides a confusing array of data with respect to the number of DMEPOS suppliers that would be affected by the surety bond requirement. For example, in the impact analysis section, in estimating the costs of obtaining surety bonds, the commenter stated that we assume that approximately 99,000 suppliers will be involved and that the average annual cost of a bond will be \$2,000. However, in the section of the proposed rule summarizing the collection of information requirements, the commenter noted that we estimate that approximately 116,500 DMEPOS suppliers will comply with the surety bond requirement.

Response: As previously stated, we have reviewed and revised our regulatory impact analysis in this final rule to address matters such as those raised by the commenter.

Comment: One commenter stated that the August 1, 2007 proposed rule requires DMEPOS suppliers to have their financial statements audited each year. The commenter noted that many DMEPOS suppliers have external firms audit their annual financial statements. The commenter believed that the annual cost for DMEPOS suppliers to audit financial statements would be exorbitant and would exceed the original intent of the surety bond requirement.

Response: While we agree that a surety may require that a supplier provide audited financial statements as part of the surety's review and evaluation process, we did not propose, nor does this final rule adopt, provisions that require a DMEPOS supplier to have its financial statements audited on an annual basis.

Comment: Many commenters indicated that some DMEPOS suppliers are already required by State or Federal entities (for example, Medicaid) to obtain a surety bond at an approximate cost of \$2,000 annually in order to provide DMEPOS to consumers. The commenters stated that it would be a financial burden to pay for both their current surety bond and a surety bond that comports with this final rule.

Response: The non-Medicare surety bond to which the commenter refers covers financial losses associated with those other medical programs. We believe that by adopting a surety bond requirement, we will protect the Medicare program and its beneficiaries from unscrupulous suppliers or suppliers who lack the financial resources to operate a legitimate business organization. We note that we have already exempted government-operated DMEPOS suppliers who have a comparable surety bond under State law from the surety bond requirement. Besides already possessing a surety bond under State law, government-operated DMEPOS suppliers are financially more secure than other DMEPOS suppliers because of their ability to tax. Therefore, we have exempted them from the surety bond requirement.

Comment: Several commenters stated that although DMEPOS account for only a small part of Medicare spending, we are trying to reduce reimbursement to DMEPOS suppliers even further through this final rule. One commenter suggested that the surety bond requirement is another CMS rule that is

designed to put small DMEPOS suppliers out of business.

Response: We disagree with the assertion that the rule is designed to push small DMEPOS suppliers out of the Medicare program. It is true that we believe it is essential to implement the DMEPOS surety bond requirement to reduce fraud and abuse in the Medicare program and to protect Medicare beneficiaries from unscrupulous suppliers. However, we note that a number of the exceptions to the bond requirement will apply to small suppliers, such as physician offices. We believe this achieves an appropriate balance between the need to protect the Medicare Trust Fund and our interest in maintaining the presence of small suppliers in the Medicare program.

Comment: One commenter observed that the January 28, 1998 proposed rule sought to require a DMEPOS supplier to obtain a surety bond for every TIN under which a supplier billing number was issued. Under this proposal, a DMEPOS supplier with more than one location would have been required to obtain only a single surety bond. The commenter stated it would be unreasonable for us to now require a DMEPOS supplier with more than one location to obtain more than one surety bond. Therefore, the commenter urged us to require DMEPOS suppliers to obtain a surety bond for each TIN or "some comparable level of 'aggregation'" rather than for each supplier location or NPI. This would minimize the negative impact of the requirement.

Other commenters stated that we do not adequately provide the reasoning behind the transition from the TIN to the NPI and do not analyze the impact of the decision on the DMEPOS industry.

Response: We note that the NPI was not implemented back in 1998, which is why the TIN was used instead. In fact, the HIPAA Administrative Simplification Standard Unique Health Identifier for Health Care Providers; Final Rule, commonly referred to as the National Provider Identifier; Final Rule, was not published until January 23, 2004. With NPIs now the standard for identifying suppliers and their subparts, and in light of the fact that each DMEPOS practice location must enroll separately in the Medicare program (note there is an exception for sole proprietorships), we believe it is appropriate for a separate surety bond to be required for each practice location or NPI obtained for DMEPOS billing purposes. This will provide CMS, the NSC, and law enforcement an easy method to identify ownership, to

determine whether adverse legal actions have been previously imposed, and to determine the value of the bond that each DMEPOS supplier must obtain and maintain in order to participate in the Medicare program. It is also important to remember that the greater the number of NPIs a supplier organization has, the proportionately more practice locations the organization tends to have and, in turn, the larger the amount of Medicare funds for which it tends to bill. Since each of these factors can enhance the overall risk to the Medicare Trust Fund, we have determined that the NPI, rather than the TIN, is more closely tied to the level of enrollment risk, and thus, should be used in lieu of the TIN.

Comment: A commenter stated that the MMA makes clear that the Congress had great concerns about the impact of remedial legislation on small DMEPOS suppliers. For example, section 154 of the MMA required CMS to give special attention to developing a competitive bidding program to ensure that small suppliers are not driven from the market by a system that gives a competitive advantage to larger or national DMEPOS suppliers. The commenter also stated that the surety bond requirement undermines the Congressional intent, and thus places smaller DMEPOS suppliers at a competitive disadvantage.

Response: We disagree with the commenter. While our competitive bidding program for DMEPOS suppliers, which the implementation has been delayed by the MIPPA as previously noted in this final rule, did include protections for small businesses to participate in this program, we do not agree that the Congress intended that all small suppliers of DMEPOS be exempt from the surety bond requirement specified in section 4312(a) of the BBA. In addition, since almost all DMEPOS suppliers are considered small businesses by the Small Business Administration (SBA) definition, it is not practical to establish an exception for DMEPOS suppliers based on revenue alone.

B. Existing DMEPOS Suppliers

1. Number Participating

The National Supplier Clearinghouse (NSC) issues 10-digit NSC supplier numbers to suppliers that bill Medicare for DMEPOS items and services. Some DMEPOS suppliers operate at multiple locations while others operate at a single location. Suppliers that are part of a single firm share the first 6 digits of the 10-digit NSC supplier number, with the last 4 digits set equal to 0001, 0002, and so on, to denote individual locations. In the following discussion,

we will refer to the first 6 digits as the “6-digit NSC supplier number” to represent individual suppliers, while the 10-digit number represents individual supplier locations.

This distinction is important for the impact analysis because: (1) DMEPOS suppliers, except sole proprietorships, are required to obtain a distinct NPI for each enrolled DMEPOS practice location, and in this final rule we have adopted the NPI as the basis for obtaining a surety bond; and (2) accreditation organizations generally charge one fee for a supplier’s first location, and a lower fee for subsequent locations. Some of the accreditation organizations also offer lower accreditation fees to small suppliers, which typically have few locations.

In March 2008, there were 113,154 unique 10-digit NSC numbers and approximately 58,000 unique 6-digit NSC numbers. Our review indicates that there are approximately 50 Medicare-enrolled DMEPOS suppliers that are both sole proprietorships and have multiple locations. Therefore, we estimate that the total number of NPIs currently associated with Medicare-enrolled DMEPOS suppliers is only very slightly less than the total number of 10-digit NSC numbers. For purposes of this impact analysis, we will assume that there are 113,000 NPIs associated with Medicare-enrolled DMEPOS suppliers. Unless noted otherwise, this impact analysis will be based on the NPI, rather than the 6-digit or 10-digit NSC number.

In addition, unless otherwise stated, the term “supplier” refers to an

individually-enrolled location with its own NPI; for purposes of our discussion, therefore, we will assume that there are approximately 113,000 DMEPOS suppliers—one for each unique NPI.

Table 3 identifies the principal categories of DMEPOS suppliers and the number of suppliers within each category as of September 2008. Note that because a DMEPOS supplier may fall into multiple categories, the number of suppliers listed below significantly exceeds the actual number of suppliers—113,000—that are enrolled in Medicare. Hence, one should not assume, for instance, that there are 54,000 pharmacies enrolled in Medicare; we estimate that the actual figure is approximately 45,000.

TABLE 3—CATEGORIES OF DMEPOS SUPPLIERS AS OF SEPTEMBER 2008 (DENOTED BY NPI)

DMEPOS supplier type	Number of suppliers
Pharmacies	54,000
Physicians (including Podiatrists and Optometrists)	30,700
Medical Supply Companies with Orthotic Personnel, Prosthetic Personnel, Registered Pharmacist, or Respiratory Therapist	16,600
Medical Supply Companies without Orthotic Personnel, Prosthetic Personnel, Registered Pharmacist, or Respiratory Therapist ..	16,100
Opticians	13,500
Oxygen and Equipment Suppliers	12,400
Orthotic and Prosthetic Personnel	10,800
Grocery or Department Stores	7,000
Nursing Facilities	4,000
Independently Practicing/Billing Physical Therapists and Occupational Therapists	2,000
Other	1,500

2. Reimbursement

Table 4 contains information that identifies the amount of reimbursement allowed to DMEPOS suppliers in 2005. The statistics are based on the number of 6-digit NSC numbers at that time, or 65,984.

As explained in section H of this impact analysis, we recognize that the percentage breakdown of allowed charges in 2005 may not be precisely the same as that which exists today. For instance, Table 4 shows that approximately 10.8 percent of DMEPOS

suppliers in 2005 had allowed charges of between \$5,000–\$9,999. This does not necessarily mean that 10.8 percent of suppliers in 2007 or 2008 had allowed charges of this amount. We would, of course, prefer to have a table of NPI-allowed charge amounts over the past 12 months; however, this is not possible because use of the NPI was not mandatory until May 2008. Moreover, because we used the 2005 6-digit NSC number data in the proposed rule, we believe that—for purposes of consistency—it would be best to also use this information in the final rule. In

sum, while recognizing the potential for variations between the 6-digit number percentages and today’s NPI-based figures, we believe that such variations are modest at best and that the percentages shown in Table 4 are similar to those in 2008. Thus, if 10.1 percent of 6-digit NSC numbers received \$0 in reimbursement in 2005, this 10.1 percent figure is equally applicable to current levels of DMEPOS reimbursement; this means that 10.1 percent of the 113,000 Medicare-enrolled suppliers (based on the NPI) receive \$0 in reimbursement.

TABLE 4—TOTAL NUMBER OF SUPPLIERS LISTED BY ALLOWED CHARGES FOR DATES OF SERVICE IN CALENDAR YEAR 2005 ON 6-DIGIT UNIQUE BILLING NUMBERS

Allowed charge	Total number of DMEPOS suppliers	Percentage of total number of suppliers
\$0	6,671	10.1
\$0.01–\$999	9,168	13.9
\$1,000–\$2,499	7,092	10.7
\$2,500–\$4,999	6,744	10.2
\$5,000–\$9,999	7,117	10.8
\$10,000–\$24,999	8,896	13.5
\$25,000–\$49,999	5,478	8.3
\$50,000–\$99,999	4,026	6.1

TABLE 4—TOTAL NUMBER OF SUPPLIERS LISTED BY ALLOWED CHARGES FOR DATES OF SERVICE IN CALENDAR YEAR 2005 ON 6-DIGIT UNIQUE BILLING NUMBERS—Continued

Allowed charge	Total number of DMEPOS suppliers	Percentage of total number of suppliers
\$100,000–\$499,999	7,146	10.8
\$500,000–\$999,999	1,982	3.0
\$1,000,000–4,999,999	1,450	2.2
\$5,000,000 or more	215	0.3
Total	65,984

C. Anticipated Effects of Accreditation on DMEPOS Supplier Surety Bonding

Under this final rule, newly enrolling and existing DMEPOS suppliers not eligible for an exception will have to obtain and maintain a surety bond to enroll or maintain their billing privileges in the Medicare program. However, it is important to note that all existing DMEPOS suppliers are required to be accredited by an approved accreditation organization by September 30, 2009.

DMEPOS suppliers will incur costs for becoming accredited. Accreditation organizations will incur costs to accredit suppliers; we assume that these costs are approximately equal to the accreditation fees paid by suppliers. The cost and impact of accreditation on DMEPOS suppliers are described in a regulation titled, “Inpatient Rehabilitation Facility Prospective Payment System for Federal FY 2007; Provisions Concerning Competitive Acquisition for Durable Medical, Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Supplier” final rule (71 FR 47870) which was published in the **Federal Register** on August 18, 2006.

1. Factors Affecting the Cost Impact

As stated previously, in March 2008, there were 113,154 unique 10-digit NSC numbers. As of September 2008, there are approximately 113,000 NPIs. This total includes suppliers as well as providers and physicians that furnish items under Medicare Part B as suppliers. The distribution of locations by supplier type is very uneven across the industry. Over 90 percent of suppliers operate a single location, while some drug chains, grocery stores, optometry companies, and a few medical equipment companies have over a hundred locations.

2. Suppliers That Probably Will Not Seek a Surety Bond Due to Accreditation

Many currently-enrolled DMEPOS suppliers are small, receive relatively

little in Medicare payments, and do not specialize in DMEPOS. In 2005, as shown in Table 4, 10.1 percent of all suppliers received \$0 in allowed charges during the calendar year. This indicates that approximately 10.1 percent of DMEPOS suppliers—or, if based on the current number of NPIs, 11,413—are not actively participating and billing in the Medicare program. Based on our analysis, we believe that almost all of these DMEPOS suppliers will have their billing privileges deactivated for 12 consecutive months of nonbilling (see § 424.540) prior to the implementation of this final rule, will qualify for an exception, or will make the business decision to exit the Medicare program on or before September 30, 2009 due to the costs associated with accreditation.

Accordingly, we estimate that 60 percent (or approximately 6,848) of the approximately 11,413 suppliers that receive no payments from Medicare will exit the Medicare program due to the cost associated with accreditation and that the remaining DMEPOS suppliers who receive no annual reimbursement from Medicare will have their Medicare billing privileges deactivated or will qualify for an exception to the bonding requirement. Given that accreditation costs approximately \$3,000 for single location DMEPOS suppliers, we believe that approximately 60 percent of the DMEPOS suppliers that are participating in the Medicare program and not actively billing the program will voluntarily withdraw from the Medicare.

In addition, we believe that this estimate is consistent with the impact analysis contained in the August 18, 2006 final rule (71 FR 48406) which states that, “we assume that the 6,900 suppliers that currently receive \$0 in allowed charges will not seek accreditation.” As such, we believe that 6,848 suppliers will not seek a surety bond due to the implementation of accreditation.

3. Suppliers That Probably Will Not Seek a Surety Bond Due to Combined Costs Associated With Surety Bond and Accreditation

As stated above, many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and do not specialize in DMEPOS. In 2005, approximately 45.6 percent of all DMEPOS suppliers received between \$1 and \$9,999, and an additional 13.5 percent of DMEPOS suppliers received between \$10,000 and \$24,999. Applying these percentages to the 113,000 current NPIs in the DMEPOS arena, we estimate that approximately 51,528 currently-enrolled DMEPOS suppliers receive annual reimbursement between \$1 and \$9,999 and approximately 15,255 DMEPOS suppliers receive annual reimbursement between \$10,000 and \$24,999. These suppliers will have to make a business decision on whether to pay for the costs associated with accreditation and a surety bond. Accreditation is for a 3-year period. The impact section of the August 18, 2006 final rule estimated that accreditation fees will be approximately \$3,000 for a DME supplier, or \$1,000 per year. The estimated average cost per year for a surety bond would be \$1,500. (Note that this is \$500 lower than the \$2,000 per year figure listed in the proposed rule. This is due to our decision to reduce the bond amount from \$65,000 to \$50,000.) We thus believe that combined costs for both accreditation and a surety bond would be approximately \$2,500 per year.

We estimate that approximately 40 percent (or 20,611) of the approximately 51,528 suppliers that receive between \$1 and \$9,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. The remaining 60 percent will consist of, naturally, suppliers that chose to remain in the program and suppliers that qualify for an exemption to the surety bond requirement. Indeed, a significant number of the physicians

and NPPs that qualify for such an exception are relatively small billers.

Furthermore, we estimate that approximately 30 percent (or 4,577) of the approximately 15,255 that receive between \$10,000 and \$24,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. The remaining 70 percent will consist of suppliers that chose to remain in the program and suppliers that would qualify for an exemption to the surety bond requirement.

4. Suppliers That Meet an Exception to the Surety Bond Requirement

Section 424.57(c)(26)(ii) establishes exceptions to the surety bond requirement for the following organizations and individuals:

- Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DME supplier has provided CMS with a comparable surety bond under State law, and if it does not have any unpaid claims, CMPs or assessments.
- State-licensed orthotic and prosthetic personnel operating in private practice and selling only orthotics, prosthetics and/or supplies if the supplier does not have any unpaid claims, CMPs, or assessments;
- Physicians and NPPs, as defined in section 1842(b)(18) of the Act, furnishing DMEPOS to the physician or NPP's own patients as part of his or her professional service; and
- State-licensed physical therapists and occupational therapists operating in private practice and furnishing prosthetics orthotics and/or supplies to the therapist's own patients as part of his or her professional service, and who does not have any unpaid claims, CMPs, or assessments.

As indicated in Table 3, there are approximately 10,800 orthotic and prosthetic personnel operating independently of a medical supply company, approximately 30,700 physicians (for example, podiatry and orthopedic/orthopedic surgery) and approximately 2,000 NPPs—specifically, physical and occupational therapists—who qualify for an exemption to the surety bond requirement. There are also approximately 35 government-operated DMEPOS suppliers. This means that 43,535 DMEPOS suppliers are eligible for an exemption from the surety bond requirement.

We recognize, however, that it is unlikely that all 43,545 of these suppliers will be exempt. As already indicated, the figures in Table 3 include

those suppliers that qualify as more than one supplier type. To illustrate, a physician who operates his or her own DMEPOS supply company may have indicated on his CMS-855S enrollment application that he is both a physician and a supply company. Clearly, such an individual would not qualify for the physician exemption. Furthermore, even those individual practitioners that only identified themselves as physicians, physical therapists, orthotic personnel, etc., may not meet the criteria for the exemption due to the composition of their practice. For instance, a physical therapist's practice may be one-half owned by a DMEPOS supply company, in which case the physical therapist would not qualify for an exemption.

For purposes of this impact analysis, we will assume that 35 percent of the 43,545 individual practitioners enrolled as DMEPOS suppliers—or 15,241—will not qualify for an exception to the surety bond requirement. We believe that 35 percent is a high-end estimate and that, in all probability, more than 15,241 practitioners will meet an exception.

D. Surety Bond Costs for Currently Enrolled DMEPOS Suppliers

While the costs of a surety bond will vary by surety, we estimate that the surety bond requirement as specified in § 424.57(d) is \$106.2 million annually. This cost is based on the factors identified below.

1. Number of Currently Enrolled DMEPOS Suppliers That Must Obtain a Surety Bond

We derived the number of presently enrolled DMEPOS suppliers that must obtain a surety bond in the following manner:

Step A—Subtracted the number of DMEPOS suppliers (6,848) that we estimated would exit the program based on implementation of accreditation from the total number of NPIs associated with DMEPOS suppliers. The result was 106,152 suppliers.

Step B—Subtracted the estimated number of suppliers (25,188) that we believe will exit the Medicare program due to the combined costs associated with accreditation and a surety bond from the sum in Step A. The result was 80,964 suppliers.

Step C—Subtracted the estimated number of suppliers (15,241) eligible for an exception to the surety bond amount from the sum in Step B. The result was 65,723 suppliers.

2. Number of New DMEPOS Suppliers That Will Need To Obtain a Surety Bond

Since any DMEPOS supplier seeking to enroll in the Medicare program on or after October 1, 2009 is required to meet all of supplier standards at § 424.57, including the accreditation standards at § 424.57(c)(22) through § 424.57(c)(25), we believe that a smaller number of applicants will apply to enroll in the Medicare program as a DMEPOS supplier after this date.

Before the implementation of accreditation, the NSC received approximately 12,000 initial enrollment applications per year, of which roughly one-half (or 6,000) were approved. After the full implementation of accreditation, we expect that the annual number of initial applications will fall to 6,000, of which approximately 2,000 will be approved. However, given the exceptions established in this final rule, it is likely that a number of these new suppliers will qualify for an exemption to the surety bond requirement. Nevertheless, for purposes of our analysis, we used the higher 2,000 figure to account for the possibility that the number of new DMEPOS suppliers in a given year may slightly exceed our expectations.

3. Cost of a Bond

Based on information received from the industry, we estimated that the average bond cost is approximately \$1,500, or 3 percent of the value of a \$50,000 bond. We multiplied the number of remaining suppliers (65,723) by \$1,500, which resulted in a figure of approximately \$98.6 million. We further estimated that no more than one-half of 1 percent of DMEPOS suppliers that are subject to the surety bond requirement (or 329 out of 65,723) have had a final adverse action imposed against them within the last 10 years and continue to participate in the Medicare program. For these suppliers, the average number of final adverse actions will be one, which will thus mandate a bond amount of \$100,000—or \$50,000 more than the base bond amount. Therefore, if we multiply 329 by the cost of the additional \$50,000 bond amount (or \$1,500), the total is \$493,500, which when added to the \$98.6 million amount identified above, results in \$99.1 million. We then add, as explained above, the estimated 2,000 new DMEPOS suppliers that will enroll in the Medicare program each year. With an average bond cost of \$1,500, this adds another \$3 million. Thus, the annual costs of the surety bond

increases from \$99.1 million to \$102.1 million.

A surety charges its underwriting fee based on the penal sum of the bond. We have determined that for this type of surety bond the industry usually has an underwriting charge of 2 to 3 percent. We believe that there is little variation of the charge based on geographical location or type of DMEPOS supplier although the DMEPOS supplier's financial average soundness probably will be a factor in the rate charged by the surety for the bond. We are unable to make an estimate of the range of financial soundness of DMEPOS suppliers, or its impact on the cost of surety bonds for Medicare.

4. Paperwork Costs for DMEPOS Suppliers

As already stated, we estimate that 65,723 currently-enrolled DMEPOS suppliers and 2,000 new DMEPOS suppliers per year will be subject to the surety bond requirement. We estimated that the year 1 implementation costs will be approximately \$4.1 million and that the annual implementation costs thereafter to be approximately \$180,000 per year.

To calculate the cost associated with the implementation of the surety bond in year 1, we calculated the cost of completing the revised Medicare enrollment application (CMS-855S) at \$20 per hour along with our estimate that it will take on average 3 hours to complete the information collection associated with surety bond.

Using this information, we multiplied 65,723 currently-enrolled DMEPOS suppliers by 3 hours to derive the time associated with completing this new information collection requirement. The result was 197,169 hours (65,723 × 3 hours). We then multiplied the result (197,169) hours times \$20 per hour to calculate the costs for existing DMEPOS suppliers subject to the bonding requirement to complete the information collection associated with the implementation of the surety bond requirement. The result equaled \$3,943,380. Similarly, we used the same calculation for newly enrolling DMEPOS suppliers and calculated a costs of \$120,000 (2,000 suppliers × 3 hours × \$20 per hour). Finally, we are assuming that a maximum of 1,000 suppliers will incur costs to update or change their surety. The resulting costs would equal \$60,000 (1,000 suppliers × 3 hours × \$20 per hour). Thus, we estimate that the paperwork burden associated with the surety bond is \$4,063,380 (\$3,943,380 + \$120,000) in year one and \$180,000 annually thereafter.

5. Total Costs

Based on the information identified in sections IV.D.1. through IV.D.4. of this final rule, we estimate that the total cost of the surety bond requirement in its first year will be approximately \$106.2 million. The cost in each subsequent year will be roughly \$102.3 million.

E. Impact on Beneficiary Access

As already discussed, we believe that 6,848 DMEPOS suppliers will exit the Medicare program as a result of the implementation of accreditation, irrespective of whether these suppliers qualify for a surety bond exemption. This will result in 106,152 suppliers remaining in the Medicare program. Starting from this figure, we will calculate the number of DMEPOS suppliers that will leave Medicare due to the surety bond requirement.

We previously estimated that 25,188 DMEPOS suppliers will exit the Medicare program due to the combined costs of the surety bond and accreditation requirements. This leaves 80,964 suppliers. If we were to assume that there are 15,241 suppliers that are eligible for an exception to the bonding requirement, 65,723 DMEPOS suppliers are left. We thus estimate that this many DMEPOS suppliers will remain in Medicare after the implementation of the surety bond requirement.

We believe that the majority of remaining DMEPOS suppliers will consist of three categories of suppliers: Pharmacies (whether large or small, chain or non-chain), physicians and NPPs who qualify for an exemption, and larger medical supply companies. Pharmacies and large medical supply companies are likely to remain in the Medicare program because, notwithstanding the cost of the bond, they have the revenues to more than offset said cost—including even those large chain pharmacies that will need to obtain a bond for each location. Those physicians and NPPs that qualify for an exemption, meanwhile, are likely to remain in Medicare for this very reason. We believe that many beneficiaries in non-rural areas, where there are a high number of chain pharmacies—and, of course, a high percentage of physician and NPP practices—will continue to have access to DMEPOS supplies offered by these suppliers.

We estimate that approximately 20 percent of all DMEPOS suppliers are located in rural areas. We believe that the majority of DMEPOS suppliers in these areas are physician and NPPs, community pharmacies, and small medical supply distributors. For reasons already stated, many physicians and

NPPs will be exempt from the surety bond requirement; as such, we do not foresee a significant decrease in the number of such rural practitioners who offer DMEPOS suppliers. Nor do we expect many community pharmacies to exit the program notwithstanding the need for them to obtain a bond. We do however recognize that a number of rural medical supply companies may withdraw from the Medicare program. However, we believe that much of the business conducted by these suppliers will be assumed by community pharmacies, physicians, NPPs, and mail-order medical supply companies; in fact, it is quite common for rural beneficiaries who are unable to access a local medical supply company to utilize mail-order services.

While we expect that some DMEPOS suppliers in rural areas will exit the Medicare program, we do not believe that this figure will be significant, nor do we believe that overall beneficiary access will be substantially curtailed. Nevertheless, to help Medicare beneficiaries in both rural and non-rural areas locate a qualified replacement DMEPOS supplier, we will conduct education and outreach efforts to ease the transition from a departing DMEPOS supplier to a DMEPOS supplier that will remain in the program.

The category of DMEPOS suppliers that will arguably be most affected by the imposition of the surety bond requirement, at least in terms of gross expenditures, is large, publicly-traded chain pharmacies. These suppliers, as already discussed, do not qualify for a surety bond exemption. Some chains have several hundred locations. Thus, for instance, a pharmacy chain that has 300 locations, each denoted by a separate NPI, will be required to obtain a bond for each site. With an annual bond cost of \$1,500, the yearly cost of the surety bond requirement for the chain organization would be \$450,000.

F. Alternatives Considered for DMEPOS Suppliers

The RFA requires agencies to analyze options for the regulatory relief of small entities. In compliance with section 604 of the RFA, therefore, we have incorporated several options designed to minimize the burden of the surety bond requirement—both a stand-alone requirement and when implemented in conjunction with the accreditation provisions found at § 424.58.

First, with respect to accreditation, we have approved multiple accreditation organizations that serve smaller suppliers, as well as accreditation organizations that will be responsible for only surveying the streamlined

quality standards for compliance and not providing any consultative services that may increase the time and cost of the survey process. Also, we believe that unannounced surveys will reduce the time and cost involved in suppliers' receiving and reviewing documents prior to the survey.

Second, we have reduced the surety bond amount from \$65,000 to \$50,000, in part to ease the economic impact on small, rural DMEPOS suppliers. Rather than a \$2,000 per year cost for a surety bond, the establishment of a \$50,000 bond amount will reduce the annual cost to \$1,500. This reduction will not, in our view, will help ensure that small, DMEPOS suppliers continue to participate in the Medicare program.

Finally, we have established several exceptions to the surety bond requirement. These exemptions apply almost exclusively to small businesses—specifically, physician and NPP practices—and will no doubt ease the economic impact on such businesses in both rural and non-rural areas.

For reasons already explained, we were unable to establish exceptions to the bond requirement for other types of small entities, such as single-site community pharmacies. Nevertheless, by reducing the bond amount to the statutory minimum and by creating those exceptions that were legally permissible, we believe that we have taken concrete steps to ease the economic burden on small business to the maximum extent permitted by section 4312(a) of the BBA.

G. Uncertainty

There are at least four important sources of uncertainty in estimating the impact of surety bonds on DMEPOS suppliers. First, our estimates assume that the vast majority of current DMEPOS suppliers with positive Medicare payments will obtain and maintain a surety bond. As noted previously, many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and do not specialize in DMEPOS. We assume that suppliers that currently receive no Medicare allowed charges will choose not to seek accreditation and a surety bond, and that many of the suppliers with allowed charges between \$1 and \$10,000 may decide not to incur the costs of accreditation.

Second, it is unclear how high or low surety bond or accreditation fees will be in the future. With required

accreditation causing more suppliers to seek accreditation, fees may fall if the accreditation organizations can enjoy economies of scale as they expand. This would lessen the impact on DMEPOS suppliers.

Third, the timing of competitive bidding may impact some DMEPOS suppliers' decision to continue to participate in the Medicare program. With the delay in the implementation of the Competitive Bidding Program as mandated by the MIPPA, we cannot calculate the impact that competitive bidding will have on existing DMEPOS suppliers continuing to participate in Medicare.

Finally, as discussed in section B of this impact analysis, we recognize that the percentage breakdown of allowed charges in 2005, as described in Table 4, may not be precisely the same as that which currently exists. It is certainly possible that the use of allowed charge data based on the NPI, rather than the 6-digit NSC number, will lead to a greater percentage of suppliers falling into the category of "small billers," for a single location (that is, an NPI-specific site) is generally likely to receive less reimbursement than an entity with multiple locations (that is, an entity denoted by a 6-digit NSC number).

Yet we believe that any such increase in the percentage of small billers will be minor. Many of these NPI-specific sites are locations that are part of large chain pharmacy organizations; such pharmacy locations often receive significant levels of Medicare reimbursement. In other words, while the change from the 6-digit NSC number to the NPI as the primary supplier identifier greatly increased the number of DMEPOS suppliers, many of these "new" suppliers were chain pharmacy locations that could not be classified as "small billers." As such, we are not entirely convinced that the increase in DMEPOS suppliers will result in a concomitant rise in the overall percentage of small billers. Still, we cannot rule out this possibility and thus concede that this issue represented an element of uncertainty in our impact analysis.

H. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 6 we have prepared an accounting statement. This statement, it should be noted, addresses only the costs and monetary transfers

associated with the surety bond requirement. It does not address, from a strictly monetary standpoint, the prospective financial benefits of the bond requirement. While we, as explained in the preamble, expects the bond requirement to provide significant program integrity benefits for Medicare on the grounds that we will be able to recoup otherwise uncollectible overpayments, CMPs, and assessments and that unscrupulous DMEPOS suppliers will be deterred from entering the Medicare program, it is impossible for us to quantify these benefits in monetary terms. We cannot predict how many potentially fraudulent DMEPOS suppliers will be kept out of the Medicare program, nor can we determine for certain how much money Medicare will recoup from said overpayments, CMPs, and assessments.

The cost section addresses the data discussed in section IV.D. of this final rule. The monetary transfers section contains information on the transfer of Medicare reimbursement from those DMEPOS suppliers that will leave the Medicare program as a result of the surety bond requirement (as described in section IV.D.1. of this final rule) to those DMEPOS suppliers that will assume the DMEPOS business of these departing suppliers. As previously stated, we estimated that approximately 30 percent (or 4,577) of the approximately 15,255 DMEPOS suppliers that receive between \$10,000 and \$24,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. We further estimated that roughly 40 percent (or 20,611) of the approximately 51,528 suppliers that receive between \$1 and \$9,999 annually from Medicare will exit the Medicare program because of these combined costs. For purposes of this assessment statement, we used the midpoint of the two aforementioned categories (or \$17,500 and \$5,000, respectively) as the amount of annual reimbursement these suppliers receive. As such, we multiplied 20,611 by \$5,000 and arrived at \$103,055,000, and multiplied 4,577 by \$17,500 to obtain a figure of \$80,097,500. Therefore, we estimate that approximately \$183.2 million in annual Medicare reimbursement will be paid to existing or new DMEPOS suppliers in lieu of those suppliers exiting the Medicare program.

TABLE 6—CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS

Category Surety bond requirement	In millions
COSTS	
Annualized Monetized Transfers Using the 7% Discount Rate	102.8.
Annualized Monetized Transfers Using the 3% Discount Rate	102.7.
Who is Affected?	DMEPOS Suppliers.
TRANSFERS	
Annualized Monetized Transfers Using the 7% Discount Rate	183.2.
Annualized Monetized Transfers Using the 3% Discount Rate	183.2.
From Who to Whom?	Departing DMEPOS Suppliers to Current or New DMEPOS Suppliers.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart D—To Whom Payment Is Ordinarily Made

■ 2. Section 424.57 is amended by—

■ A. Amending paragraph (a) by adding the following definitions in alphabetical order: “Assessment”, “Authorized surety”, “Civil money penalty”, “Final adverse action”, “Government-operated supplier”, “National Supplier Clearinghouse (NSC)”, “Penal sum”, “Rider”, “Sufficient evidence”, “Surety bond”, and “Unpaid claim”.

■ B. In paragraph (a), in the definition of “DMEPOS supplier”, the cross-reference “paragraph (c)” is removed and the cross-reference “paragraphs (c) and (d)” are added in its place.

■ C. Adding paragraph (c)(26).

■ D. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f).

■ D. Adding a new paragraph (d).

■ E. In newly redesignated paragraph (e), the cross-reference “paragraphs (b) and (c)” is removed and the cross-reference “paragraphs (b), (c), and (d)” is added in its place.

The additions read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) * * *

Assessment means a sum certain that CMS or the Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act or as specified in this chapter.

Authorized surety means a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

Civil money penalty (CMP) means a sum that CMS has the authority, as implemented by 42 CFR 402.1(c); or OIG has the authority, under section 1128A of the Act or 42 CFR part 1003, to impose on a supplier as a penalty.

* * * * *

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges;

(ii) Suspension or revocation of a license to provide health care by any State licensing authority;

(iii) Revocation or suspension by an accreditation organization;

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)(A)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(v) An exclusion or debarment from participation in a Federal or State health care program.

Government-operated supplier is a DMEPOS supplier owned or operated by a Federal, State, or Tribal entity.

* * * * *

National Supplier Clearinghouse (NSC) is the contractor that is responsible for the enrollment and re-enrollment process for DMEPOS suppliers.

Penal sum is the maximum obligation of the surety if a loss occurs.

Rider means a notice issued by a surety that a change in the bond has occurred or will occur.

Sufficient evidence means documents CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier.

Surety bond means a bond issued by one or more sureties under 31 U.S.C. 9304 through 9308 and 31 CFR parts 223, 224, and 225.

Unpaid claim means an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible, plus accrued interest that is effective 90 days after the date of the notice sent to the DMEPOS supplier of the overpayment. If a written agreement for payment, acceptable to CMS, is made, an *unpaid claim* also means a Medicare overpayment for which the DMEPOS supplier is responsible, plus accrued interest after the DME supplier's default on the arrangement.

* * * * *

(c) * * *

(26) Must meet the surety bond requirements specified in paragraph (d) of this section.

* * * * *

(d) *Surety bonds requirements.*
(1) *Effective date of surety bond requirements.*

(i) *DMEPOS suppliers seeking enrollment or with a change in ownership.* Except as provided in paragraph (d)(15) of this section, beginning May 4, 2009, DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS must meet the requirements of paragraph (d) of this section for each assigned NPI for which the DMEPOS

supplier is seeking to obtain Medicare billing privileges.

(i) *Existing DMEPOS suppliers.*

Except as provided in paragraph (d)(15) of this section, beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d) of this section for each assigned NPI to which Medicare has granted billing privileges.

(2) *Minimum requirements for a DMEPOS supplier.*

(i) A supplier enrolling in the Medicare program, making a change in ownership, or responding to a revalidation or reenrollment request must submit to the NSC a surety bond from an authorized surety of \$50,000 and if required by the NSC an elevated bond amount as described in paragraph (d)(3) of this section with its paper or electronic Medicare enrollment application (CMS-855S, OMB number 0938-0685). The term of the initial surety bond must be effective on the date that the application is submitted to the NSC.

(ii) A supplier that seeks to become an enrolled DMEPOS supplier through a purchase or transfer of assets or ownership interest must submit to the NSC a surety bond from an authorized surety of \$50,000 and if required by the NSC an elevated bond amount as described in paragraph (d)(3) of this section that is effective from the date of the purchase or transfer in order to exercise billing privileges as of that date. If the bond is effective at a later date, the effective date of the new DMEPOS supplier billing privileges is the effective date of the surety bond as validated by the NSC.

(iii) A DMEPOS supplier enrolling a new practice location must submit to the NSC a new surety bond from an authorized surety or an amendment or rider to the existing bond, showing that the new practice location is covered by an additional base surety bond of \$50,000 or, as necessary, an elevated surety bond amount as described in paragraph (d)(3) of this section.

(3) *Elevated surety bond amounts.*

(i) If required, a DMEPOS supplier must obtain and maintain a base surety bond in the amount of \$50,000 as specified in paragraph (d)(2) of this section and an elevated surety bond in the amount prescribed by the NSC as described in paragraph (d)(3)(ii) of this section.

(ii) The NSC prescribes an elevated surety bond amount of \$50,000 per occurrence of an adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment, as defined in paragraph (a) of this section.

(4) *Type and terms of the surety bond.*

(i) *Type of bond.* A DMEPOS supplier must submit a bond that is continuous.

(ii) *Minimum requirements of liability coverage.*

(A) The terms of the bond submitted by a DMEPOS supplier for the purpose of complying with this section must meet the minimum requirements of liability coverage (\$50,000) and surety and DMEPOS supplier responsibility as set forth in this section.

(B) CMS requires a supplier to submit a bond that on its face reflects the requirements of this section. CMS revokes or denies a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of paragraph (d) of this section.

(5) *Specific surety bond requirements.*

(i) The bond must guarantee that the surety will, within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, CMPs, or assessments, pay CMS a total of up to the full penal amount of the bond in the following amounts:

(A) The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.

(B) The amount of any unpaid claims, CMPs, or assessments imposed by CMS or OIG on the DMEPOS supplier, plus accrued interest.

(ii) The bond must provide the following: The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

(iii) If the DMEPOS supplier fails to furnish a bond meeting the requirements of paragraph (d) of this section, fails to submit a rider when required, or if the DMEPOS supplier's billing privileges are revoked, the last bond or rider submitted by the DMEPOS supplier remains in effect until the last day of the surety bond coverage period and the surety remains liable for unpaid claims, CMPs, or assessments that—

(A) CMS or the OIG imposes or asserts against the DMEPOS supplier based on overpayments or other events that took place during the term of the bond or rider; and

(B) Were imposed or assessed by CMS or the OIG during the 2 years following the date that the DMEPOS supplier failed to submit a bond or required rider, or the date the DMEPOS supplier's billing privileges were terminated, whichever is later.

(6) *Cancellation of a bond and lapse of surety bond coverage.*

(i) A DMEPOS supplier may cancel its surety bond and must provide written notice at least 30 days before the

effective date of the cancellation to the NSC and the surety.

(ii) Cancellation of a surety bond is grounds for revocation of the DMEPOS supplier's Medicare billing privileges unless the DMEPOS supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.

(iii) If CMS receives notification of a lapse in bond coverage from the surety, the DMEPOS supplier's billing privileges are revoked. During this lapse, Medicare does not pay for items or services furnished during the gap in coverage, and the DMEPOS supplier is held liable for the items or services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for the items or services).

(iv) The surety must immediately notify the NSC if there is a lapse in the surety's coverage of the DMEPOS supplier's coverage.

(7) *Actions under the surety bond.* The bond must provide that actions under the bond may be brought by CMS or by CMS contractors.

(8) *Required surety information on the surety bond.* The bond must provide the surety's name, street address or post office box number, city, state, and zip code.

(9) *Change of surety.* A DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the NSC at least 30 days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods. If a gap in coverage exists, the NSC revokes the supplier's billing privileges and does not pay for any items or services furnished by the DMEPOS supplier during the period for which no bond coverage was available. If a DMEPOS supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond. The previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.

(10) *Parties to the surety bond.* The surety bond must name the DMEPOS supplier as Principal, CMS as Oblige, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety.

(11) *Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond.*

(i) CMS revokes the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions. Notwithstanding paragraph (e) of this section, the revocation is effective the date the bond lapsed and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier.

(ii) CMS denies billing privileges to a supplier if the supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified with this subpart and CMS instructions.

(12) *Evidence of DMEPOS supplier's compliance.* CMS may at any time require a DMEPOS supplier to show compliance with the requirements of paragraph (d) of this section.

(13) *Effect of subsequent DMEPOS supplier payment.* If a surety has paid an amount to CMS on the basis of liability incurred under a bond and CMS subsequently collects from the DMEPOS supplier, in whole or in part, on the unpaid claim, CMPs, or assessment that was the basis for the surety's liability, CMS reimburses the surety the amount that it collected from the DMEPOS supplier, up to the amount paid by the surety to CMS, provided the surety has no other liability to CMS under the bond.

(14) *Effect of review reversing determination.* If a surety has paid CMS on the basis of liability incurred under a surety bond and to the extent the DMEPOS supplier that obtained the

bond is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS refunds the DMEPOS supplier the amount the DMEPOS supplier paid to CMS to the extent that the amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

(15) *Exception to the surety bond requirement.*

(i) *Qualifying entities and requirements.*

(A) Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DMEPOS supplier has provided CMS with a comparable surety bond under State law.

(B) State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics are provided an exception to the surety bond requirement if—

(1) The business is solely-owned and operated by the orthotic and prosthetic personnel, and

(2) The business is only billing for orthotic, prosthetics, and supplies.

(C) Physicians and nonphysician practitioners as defined in section 1842(b)(18) of the Act are provided an exception to the surety bond requirement when items are furnished only to the physician or nonphysician practitioner's own patients as part of his or her physician service.

(D) Physical and occupational therapists in private practice are

provided an exception to the surety bond requirement if—

(1) The business is solely-owned and operated by the physical or occupational therapist;

(2) The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and

(3) The business is only billing for orthotics, prosthetics, and supplies.

(ii) *Loss of a DMEPOS supplier exception.* A DMEPOS supplier that no longer qualifies for an exception as described in paragraph (d)(15)(i) of this section must submit a surety bond to the NSC in accordance with requirements of paragraph (d) of this section within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

* * * * *

Authority: Catalog of Federal Domestic Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: May 1, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 18, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on Monday, December 22, 2008.

[FR Doc. E8-30802 Filed 12-29-08; 11:15 am]

BILLING CODE 4120-01-P

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Friday, January 2, 2009

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