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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. 04–033F; FDMS No. FSIS–2007–0045]

RIN 0583–AD18

Allowing Bar-Type Cut Turkey Operations To Use J-Type Cut Maximum Line Speeds

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to provide that turkey slaughter establishments that open turkey carcasses with Bar-type cuts may operate at the maximum line speeds established for J-type cuts if the establishment uses the specific type of shackle described in this final rule. Under this final rule, as under current regulations, the inspector in charge will reduce line speeds when, in his or her judgment, the prescribed inspection procedure cannot be adequately performed within the time available because of the health conditions of a particular flock or because of other factors. Such factors include the manner in which birds are being presented to the inspector and the level of contamination among the birds on the line.

DATES: *Effective Date:* October 8, 2008.

FOR FURTHER INFORMATION CONTACT: Patrick Burke, Risk Management Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 3543, South Building, 1400 Independence Avenue, SW., Washington, DC 20250; Telephone (202) 720–7974.

SUPPLEMENTARY INFORMATION:

Background

The Poultry Products Inspection Act (PPIA) requires post-mortem inspection of all carcasses of slaughtered poultry subject to the Act (21 U.S.C. 455(b)). Under the New Turkey Inspection (NTI) System regulation (9 CFR 381.68), one or two inspectors on each eviscerating line examine the whole carcass and viscera of each bird. The NTI System regulation provides maximum line speeds for: (1) One inspector and two inspector lines; (2) light (under 16 pounds) and heavy (16 pounds and over) turkeys; and (3) turkeys with J-type cut openings and turkeys with Bar-type cut openings.

Some turkey slaughter establishments cut a J-type opening in the turkey carcass, which is a large abdominal opening in the turkey that facilitates the removal of the viscera. These establishments use a metal or plastic device that is inserted into the cavity of the carcass to hold the hocks. Other establishments leave a section of skin intact between the vent and body opening to secure the hocks. This type of opening is called a Bar-type cut opening.

When the final NTI System regulation was published in 1985 (50 FR 37508), because of the shackles that were in use, Bar-type cut turkeys presented for inspection on a three-point suspension required an extra inspection hand motion to raise the bar-cut skin flap to observe the under side of the bar-cut skin flap and the kidney area. This extra hand motion is not necessary to inspect J-type cut turkeys. Therefore, the regulation requires a slower line speed for Bar-type cut operations than for J-type cut operations. In addition, the regulation states that the inspector in charge may reduce inspection line rates when, in his or her judgment, the prescribed inspection procedure cannot be adequately performed within the time available because the health conditions of a particular flock dictate a need for a more extended inspection (9 CFR 381.68(c)).

In 1988, a turkey slaughter establishment developed a turkey shackle that positioned the three-point hung turkey carcasses on a shackle with a 4-inch by 4-inch selector (or kickout), a 45 degree bend of the lower 2 inches, an extended central loop portion of the shackle that lowered the abdominal cavity opening of the carcasses to an angle of 30 degrees from the vertical in direct alignment with the inspector's view, and a width of 10.5 inches. This shackle allows light to illuminate the total inside surfaces of the carcass and allows FSIS inspectors to view and properly inspect the inside surfaces of the carcass with minimal manipulation. Thus, with the modified shackles, the Bar-type cut inspection hand motions are similar to the J-type cut inspection hand motions.

After this turkey slaughter establishment installed the modified shackles, FSIS conducted a study on the effectiveness of these shackles. FSIS concluded that, in a Bar-type cut operation using the modified shackle and regulatory maximum J-type cut line speeds, establishment employees and FSIS inspectors are able to perform as well as they did when using the slower, regulatory maximum Bar-type cut line speeds. FSIS also concluded that, because the modified shackle allows for modification of the inspection hand motions, use of the modified shackle decreases the inspector's work load under the Bar-type cut inspection procedure.

Under 9 CFR 381.3(b), for limited periods, the Administrator of FSIS may waive provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. Under this regulation, on July 21, 1989, the Administrator waived the NTI System regulation for the first establishment that installed the modified shackles, so that the Bar-type cut establishment could run at the maximum line speeds for J-type cut turkeys. That establishment is no longer using the modified shackle.

FSIS has, however, allowed two other establishments that installed the modified turkey shackles described above to run at the maximum line speeds for J-type cut turkeys. Under 9 CFR 381.3(b), FSIS authorized one to begin operating at the faster line speeds on June 15, 2001, and the other on March 17, 2004. FSIS reviewed in-plant trial data from these establishments, including disposition accuracy, contamination rate, microbiological characteristics, and other product characteristics. The data show no statistical difference between turkeys

processed using the modified Bar-type cut shackle running at the faster J-type cut line speeds and turkeys processed at the same establishment using the original Bar-type cut shackle (non-modified) running at the slower Bar-type cut line speeds.

On February 19, 2004, ConAgra Foods, the parent company of the two establishments that process Bar-type cut turkey carcasses with modified shackles, using the faster line speeds for J-type cuts, submitted a petition to FSIS requesting that the Agency revise its regulations to allow turkey establishments that use Bar-type cuts and modified shackles to operate under the inspection rates (line speeds) established for J-type cuts. On September 9, 2005, FSIS proposed to amend the regulations consistent with the petitioner's request (70 FR 53582).

Proposed and Final Rule Changes

This final rule amends the NTI System regulation, consistent with the petitioner's request, to provide that turkey slaughter establishments that open turkey carcasses with Bar-type cuts may operate at the maximum line speeds established for J-type cuts if the establishment uses a shackle with a 4-inch by 4-inch selector (or kickout), a 45 degree bend of the lower 2 inches, an extended central loop portion of the shackle that lowers the abdominal cavity opening of the carcasses to an angle of 30 degrees from the vertical in direct alignment with the inspector's view, and a width of 10.5 inches. The final rule provisions are the same as those that FSIS proposed. FSIS did not make any changes in the final rule based on comments received in response to the proposed rule.

Based on the in-plant trial data discussed above, FSIS has determined that product quality and safety will not be affected by allowing establishments producing Bar-cut turkeys to operate at the maximum regulatory line speeds for J-type cuts, provided these establishments use the type of shackle described in this final rule. FSIS has concluded that this rule will facilitate post-mortem inspection of turkey carcasses. For the two Bar-type cut turkey establishments that use the modified shackle to be able to run at these line speeds on a permanent basis, it is necessary that FSIS amend 9 CFR 381.68. In addition, it is necessary that FSIS amend the regulation to allow all turkey slaughter establishments that may use Bar-type cut openings to run at the maximum J-type cut line speeds, provided that such establishments use the correct shackles, and provided that the health conditions of the flock or other factors do not cause the inspector-in-charge to reduce the line speed.

Under this final rule, as under current regulations, the inspector in charge can reduce line speeds when, in his or her judgment, the prescribed inspection procedure cannot be adequately performed within the time available because of the health conditions of a particular flock. In addition, this final rule makes clear that the inspector-in-charge could reduce line speeds when the prescribed inspection procedure cannot be adequately performed within the time available because of factors other than the health conditions of the flock. This rule specifies that such factors could include the manner in which birds are being presented to the inspector for inspection and the level of contamination among the birds on the line.

Responses to Comments on the Proposal

FSIS received three comments in response to the proposed rule on allowing Bar-type cut turkey operations to use J-type cut maximum line speeds, one from an FSIS employee and two from animal rights organizations.

Comment: The FSIS employee asked whether studies have been completed to determine what effect the increase in line speed will have on the upper extremities of FSIS inspectors and establishment employees.

The commenter also questioned whether concrete guidelines would be given to inspection program personnel to assist them in making an objective decision regarding reducing line speeds.

In addition, the employee questioned whether FSIS performed baseline studies concerning the safety of those who work on the evisceration line when the initial NTI System regulation was proposed. This commenter stated that FSIS employees are ignorant as to the debilitating and potentially disabling effects that increasing line speeds have on the muscles, nerves, tendons, joints, and ligaments of their upper extremities.

Response: In 1989, based on the study of the effectiveness of the modified shackle discussed above, FSIS determined that, by eliminating the tilting motion at establishments operating with the J-type cut maximum line speeds, the inspection procedure was improved. Tilting the turkey normally required an ulner deviation of the hands, which is one of the motions thought to lead to Carpal Tunnel Syndrome. Therefore, FSIS determined that the modified shackle is ergonomically better than the traditional turkey shackle.

FSIS did not conduct baseline studies concerning the safety of those who work on the evisceration line when the initial NTI System regulation was proposed in 1984 (49 FR 44640) or finalized in 1985 (50 FR 37508). FSIS determined it was unnecessary to conduct such baseline studies because the NTI System regulation eliminated certain inspector motions. By eliminating motions, the regulation increased the safety for inspection program personnel who work on turkey evisceration lines.

FSIS does not intend to issue new guidance to inspection program personnel to assist them in making an objective decision regarding reducing line speeds. Under this rule, as under current regulations, inspection program personnel are to use their professional judgment when making a decision to reduce line speeds.

Comment: The two animal rights organizations stated that faster line speeds will result in a great deal of additional suffering to birds during shackling. One of the commenters stated that when line speeds are increased, workers grab the birds more roughly and snap their legs into shackles more violently. The other commenter stated that meat and poultry slaughter establishment workers involved in incidents of inhumane handling often explain that they were forced to mistreat animals because of the pressure of keeping up with the slaughter line. The commenter further stated that FSIS should consider the potential impact on animal treatment when proposing changes to slaughter practices, such as line speeds.

Response: FSIS believes that faster line speeds will not result in additional suffering to birds. With the increased line speed, the company may hire additional handlers with the result that the time to hang the birds remains the same. As FSIS explained in the **Federal Register** notice on the treatment of live poultry before slaughter (70 FR 56624, September 28, 2005), under the PPIA and Agency regulations, all poultry establishments must handle live poultry in a manner that is consistent with good commercial practices, which means they should be treated humanely. In this notice, FSIS also explained that the Agency considers humane methods of handling birds and humane slaughter operations a high priority and takes seriously any violations of applicable laws and regulations. Under 9 CFR 381.71, FSIS condemns poultry showing, on ante mortem inspection, certain diseases or conditions. Bruising is one condition that may result in condemnation (9 CFR 381.89). Bruises

are likely to result when birds are not treated humanely.

Executive Order 12866

This action has been reviewed for compliance with Executive Order (EO) 12866. This rule has been designated ''non-significant'' and therefore has not been reviewed by the Office of Management and Budget.

Need for the Rule

This rule is necessary to provide more production options for turkey slaughter establishments. For the two Bar-type cut turkey establishments that use the modified shackles to be able to run at the faster line speeds on a permanent basis, it is necessary that FSIS amend the regulations. In addition, it is necessary that FSIS amend the regulations to allow all turkey establishments that may use Bar-type cut openings to run at the maximum J-type cut line speeds, provided that such establishments use the correct shackles, and provided that the health conditions of the flock or other factors do not cause the inspector in charge to reduce the line speed.

Industry Overview

According to FSIS' Animal Disposition Reporting System (ADRS), the U.S. turkey industry consists of approximately 80 slaughter and processing establishments, of which 25 are considered very small, 30 are considered small, and 25 are considered large.[1] The total industry employs between 20,000 and 25,000 people in the United States, with thousands more employed in related industries, such as contract growing, product distribution, equipment manufacturing, and other affiliated services.[2]

Turkey companies are vertically integrated, meaning that they control or contract for all phases of production and processing—from breeding through delivery to retail. In a vertically integrated framework of turkey contracting, establishments (integrators) accept much of the risk of turkey growing in exchange for greater control over both the quality and quantity of birds. Usually, the contract calls for establishments to provide growers with chicks or poult hatchlings and feed from their own hatcheries and feed mills, veterinary services, medication, and field supervisors to monitor operations. The contract growers provide housing, equipment, labor, water, and all or most of the fuel and litter. Growers raise the birds until ready for shipment to the establishments. In their contractual arrangements with growers, establishments usually agree to pay a pre-established fee per pound for live turkeys plus a bonus or penalty for performance relative to other growers.[3]

In 2006, the number of turkeys raised in the United States was 262 million head, weighing an average of 24.8 pounds. In 2006, the number of pounds of turkey produced was 6.5 billion pounds. At a rate of 45 cents per pound, the value of production equaled $2.9 billion.

U.S. consumption of turkey and turkey products is estimated to be nearly 17.1 pounds per person for 2007. The most popular turkey product continues to be the whole turkey, comprising 25 percent of all turkey sales in 2006. The product distribution for turkey products is as follows: 41.1 percent to grocery stores and other retail outlets; 23.1 percent sold in commodity outlets; 21.6 percent sold to foodservice outlets; and 10 percent exported.

U.S. exports of turkey products in 2006 were 545 million pounds, comprising 9.6 percent of total turkey production. In 2006, the top four export markets for U.S. turkey were Mexico (310.0 million pounds), China (35.4 million pounds), Russia (25.2 million pounds), and Canada (21.9 million pounds).

Traditionally, turkey plants face highly seasonal demand, with most production occurring in the last quarter of the year to accommodate the increased consumption of turkeys around Christmas and Thanksgiving. Because of a shift in consumers' taste for turkey and turkey products, consumers are consuming more turkey products, such as turkey sausages, ground turkey, luncheon meat, and tray packs; pre-cooked turkey products such as deli breasts, turkey ham, and turkey bacon; and other further processed turkey products, on a year-round basis. More consumers are consuming turkey on a year-round basis because of health concerns and turkey's nutritional value, which addresses those concerns.[4] This trend in consumption reduces the excess capacity that plants were experiencing during much of the year to a more balanced production cycle year round. By supplying turkey and turkey products year round, turkey plants have been able to stabilize production rates. Stabilized production rates lower production costs because plants are able to avoid hiring, training, laying off employees, and starting up and shutting down of facilities on a seasonal basis.

Estimated Benefits

Establishments that process Bar-type cut turkeys and install the modified shackles will likely realize benefits because these establishments will be able to process more turkeys by using the J-type cut line speeds. According to ConAgra (who has petitioned FSIS to amend the regulations, consistent with this rule), by using the J-type cut line speeds, a turkey plant processing Bar-type cut turkeys can increase its production capacity by 13 percent. Also according to ConAgra, under typical pricing and operation parameters, this increase will result in $600,000 to $3,000,000 more in revenue annually per establishment. In addition, this increase in capacity for processing turkeys will allow establishments to receive a greater return on their fixed assets.

In addition to the two establishments that use Bar-type cuts that FSIS has authorized to run at the maximum line speeds for J-type cuts, any other Bar-type cut establishment also can begin using the modified shackle and faster line speeds under this final rule. If other turkey slaughter establishments produce a large volume of whole turkeys, some of these turkey establishments may decide to install the shackles to process Bar-type cut turkeys and may obtain benefits similar to those ConAgra projected in its petition.

The use of the modified shackles for Bar-type cut turkeys, compared to the traditional shackles for these turkeys, changes the presentation of the turkey so that the inspector need not manipulate the bar skin strip to observe the underside of that flap and the kidney area. Therefore, the Agency may also realize benefits because the inspectors would not be required to perform an extra hand motion. The elimination of this extra hand motion may reduce undue fatigue among turkey inspectors.

Based on data from an FSIS study at a Bar-type cut turkey plant that ran at the J-type cut maximum line speeds and used the modified shackle that met the criteria to be included in this rule, this

[1] In the preamble to the final rule entitled ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' establishments that employ between 1–9 persons and have less than $2.5 million in annual sales are considered very small; those that employ 10 to 499 persons are considered small; and those that employ 500 or more persons are considered large.

[2] National Turkey Federation Web site (*http://www.eatturkey.com/index.html*). Turkey Facts and Trivia.

[3] USDA Structural Change in U.S. Chicken and Turkey Slaughter, Michael Ollinger, James MacDonald, Milton Madison, September 2000, pp. 11–12 (ERS Agricultural Economic Report Number 787).

[4] Consumers are recognizing the health benefits of turkey as a low-fat, high-protein source. National Turkey Federation Web site.

rule will not affect product quality or safety.

Estimated Costs

The costs of the final rule will be the costs establishments incur in purchasing and installing the modified shackles. Establishments are not likely to incur these costs unless they will realize benefits. Industry sources estimate that it would cost a typical plant $55,000 (in 2006 dollars) to install the modified shackles on two assembly lines.

Regulatory Flexibility Act (RFA)

FSIS has examined the economic implications of the final rule as required by the RFA (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the RFA requires that regulatory options that would lessen the economic effect of the rule on small entities be analyzed. FSIS has determined that the final rule will not have a significant impact on a substantial number of small entities for the reasons discussed below.

One of the establishments using the modified shackle is small, and one is large. Under the final rule, turkey slaughter establishments are not required to install modified shackles and are only likely to do so should they incur profits through the faster line speed for the production of whole turkeys. Based on the ADRS data discussed above, there are about 30 small turkey slaughter establishments that could potentially install modified shackles. Very small establishments are not likely to install modified shackles because they are seasonal turkey processors.

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 inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/Regulations_&_Policies/2008_Interim_&_Final_Rules_Index/index.asp*. FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade groups, consumer interest groups, health professionals, and other individuals who have requested to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 381

Poultry products inspection, Post-mortem.

■ For the reasons discussed in the preamble, FSIS is amending 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 21 U.S.C. 451 *et seq.*

■ 2. Section 381.68 is amended as follows:

■ a. Paragraph (a) is amended by revising the first two sentences and by adding a new sentence after the second newly revised sentence;

■ b. Paragraph (c) is amended by adding ''or other factors, including the manner in which birds are being presented to the inspector for inspection and the level of contamination among the birds on the line,'' in the introductory text after the words ''particular flock''; and by revising the table and footnotes.

The revisions and additions read as follows:

§ 381.68 Maximum inspection rates—New turkey inspection system.

(a) The maximum inspection rates for one inspector New Turkey Inspection (NTI–1 and NTI–1 Modified) and two inspectors New Turkey Inspection (NTI–2 and NTI–2 Modified) are listed in the table below. The line speeds for NTI–1 and NTI–2 are for lines using standard 9-inch shackles on 12-inch centers with birds hung on every shackle and opened with J-type or Bar-type opening cuts. The line speeds for NTI–1 Modified and NTI–2 Modified are for Bar-type cut turkey lines using a shackle with a 4-inch by 4-inch selector (or kickout), a 45 degree bend of the lower 2 inches, an extended central loop portion of the shackle that lowers the abdominal cavity opening of the carcasses to an angle of 30 degrees from the vertical in direct alignment with the inspector's view, and a width of 10.5 inches. * * *

* * * * *

(c) * * *

MAXIMUM TURKEY INSPECTION RATES

Inspection system	Line configuration	Number of inspectors	Birds/minute			
			J-Type		Bar-Type	
			(<16#) light	(>16#) [1] heavy	(<16#) light	(>16#) [1] heavy
NTI–1	12–1	1	32	30	25	21
NTI–2	[2] 24–2	2	51	41	45	35
NTI–1 Modified	12–1	1	—	—	32	30
NTI–2 Modified	[2] 24–2	2	—	—	51	41

[1] This weight refers to the bird at the point of post-mortem inspection without blood or feet.
[2] The turkeys are suspended on the slaughter line at 12-inch intervals with two inspectors each looking at alternating birds at 24-inch intervals.

Done in Washington, DC, on August 29, 2008.

Alfred V. Almanza,

Administrator.

[FR Doc. E8–20551 Filed 9–5–08; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0356; Directorate Identifier 2008–NM–042–AD; Amendment 39–15661; AD 2008–18–04]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–400 Series Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD), which applies to certain Bombardier Model DHC–8–400 series airplanes. That AD currently requires inspecting all barrel nuts to determine if the barrel nuts have a certain marking, inspecting affected bolts to determine if the bolts are pre-loaded correctly, and replacing all hardware if the pre-load is incorrect. For airplanes on which the pre-load is correct, the existing AD requires doing repetitive visual inspections for cracking of the barrel nuts and cradles and replacing all hardware for all cracked barrel nuts. The existing AD also requires replacing all hardware for certain affected barrel nuts that do not have cracking, which would end the repetitive inspections for those airplanes. The existing AD also provides an optional replacement for all affected barrel nuts. This new AD requires replacing all affected barrel nuts and applying a certain compound to the affected barrel nuts and bolts. This AD results from reports of cracking in the barrel nuts at the four primary front spar wing-to-fuselage attachment joints. We are issuing this AD to detect and correct cracking of the barrel nuts at the wing front spar wing-to-fuselage joints, which could result in reduced structural integrity of the wing-to-fuselage attachments and consequent detachment of the wing.

DATES: This AD becomes effective October 14, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of October 14, 2008.

On February 13, 2008 (73 FR 8187, February 13, 2008), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008.

ADDRESSES: For service information identified in this AD, contact Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Pong Lee, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7324; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a supplemental notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that supersedes AD 2008–04–02, amendment 39–15374 (73 FR 8187, February 13, 2008). The existing AD applies to certain Bombardier Model DHC–8–400 series airplanes. That supplemental NPRM was published in the **Federal Register** on June 26, 2008 (73 FR 36285). That supplemental NPRM proposed to continue to require inspecting all barrel nuts to determine if the barrel nuts have a certain marking, inspecting affected bolts to determine if the bolts are pre-loaded correctly, and replacing all hardware if the pre-load is incorrect. For airplanes on which the pre-load is correct, that supplemental NPRM also proposed to continue to require doing repetitive visual inspections for cracking of the barrel nuts and cradles and replacing all hardware for all cracked barrel nuts. That supplemental NPRM also proposed to continue to require replacing all hardware for certain affected barrel nuts that do not have cracking, which would end the repetitive inspections for those airplanes. In addition, that supplemental NPRM also proposed to continue to provide an optional replacement for all affected barrel nuts. Finally, that supplemental NPRM also proposed to require replacing all affected barrel nuts and applying a certain compound to the affected barrel nuts and bolts.

Comments

We provided the public the opportunity to participate in the development of this AD. No comments have been received on the NPRM or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air

safety and the public interest require adopting the AD as proposed.

Costs of Compliance

This AD affects about 48 airplanes of U.S. registry.

The actions that are required by AD 2008–04–02 and retained in this AD take about 3 work hours per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the currently required actions is $11,520, or $240 per airplane, per inspection cycle.

Replacement of the hardware of a barrel nut, if required, takes about 12 work hours per airplane, at an average labor rate of $80 per work hour. Required parts cost about $800 per barrel nut. Based on these figures, we estimate the cost of a replacement to be $1,760 per barrel nut.

Application of the compound, if required, takes about 4 work hours per airplane, at an average labor rate of $80 per work hour. Based on these figures, we estimate the cost of a replacement to be $320 per application.

Authority for This Rulemaking

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

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

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–15374 (73 FR 8187, February 13, 2008) and by adding the following new airworthiness directive (AD):

2008–18–04 Bombardier, Inc. (Formerly de Havilland, Inc.): Amendment 39–15661. Docket No. FAA–2008–0356; Directorate Identifier 2008–NM–042–AD.

Effective Date

(a) This AD becomes effective October 14, 2008.

Affected ADs

(b) This AD supersedes AD 2008–04–02.

Applicability

(c) This AD applies to Bombardier Model DHC–8–400, DHC–8–401, and DHC–8–402 airplanes, certificated in any category; serial numbers 4001 and 4003 through 4176 inclusive.

Unsafe Condition

(d) This AD results from reports of cracking in the barrel nuts at the four primary front spar wing-to-fuselage attachment joints. We are issuing this AD to detect and correct cracking of the barrel nuts at the wing front spar wing-to-fuselage joints, which could result in reduced structural integrity of the wing-to-fuselage attachments and consequent detachment of the wing.

Compliance

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

Restatement of Requirements of AD 2008–04–02 With New Service Information

Inspections and Corrective Actions

(f) Within 50 flight hours after February 13, 2008 (the effective date of AD 2008–04–02), inspect all barrel nuts, part number DSC228–16, to determine if the barrel nuts are identified with a marking of LH7940T SPS 01. Inspect in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(1) If no barrel nuts are identified with a marking of LH7940T SPS 01, no further actions are required by this paragraph.

(2) If any barrel nut is found that is identified with a marking of LH7940T SPS 01, before further flight, inspect the inboard and outboard bolts to determine if the bolts are pre-loaded correctly. Inspect in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(i) If the pre-load is incorrect (i.e., the ring can be rotated), before further flight, replace all hardware at that location in accordance with the Accomplishment Instructions of the alert service bulletin.

(ii) If the pre-load is correct, before further flight, do a visual inspection for cracking of the barrel nuts and cradles in accordance with the Accomplishment Instructions of the alert service bulletin.

(A) If no cracking of the barrel nut and cradle is found, do the applicable action required by paragraph (g) of this AD.

(B) If no cracking of the barrel nut is found and only cracking of the cradle is found, no action is required by this paragraph provided that the applicable corrective action specified in paragraph (g) of this AD is done.

(C) If any cracking of the barrel nut is found, before next flight, replace all hardware only at that location in accordance with the Accomplishment Instructions of the alert service bulletin.

(g) For any barrel nuts on which no cracking of the barrel nut was found during the inspection required by paragraph (f)(2)(ii) of this AD, do the applicable corrective action specified in paragraph (g)(1), (g)(2), (g)(3), (g)(4), or (g)(5) of this AD at the compliance time specified in the applicable paragraph.

(1) If four barrel nuts having no cracking are found, do the actions specified in paragraphs (g)(1)(i), (g)(1)(ii), and (g)(1)(iii) of this AD.

(i) Within 50 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 50

flight hours until the replacement specified in paragraph (g)(1)(ii) of this AD is done.

(ii) Within 100 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, replace all hardware at the left-hand outboard location and the right-hand outboard location in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used. Replacing the barrel nuts on the outboard locations terminates the requirement to do the repetitive inspections specified in paragraph (g)(1)(i) of this AD.

(iii) Within 100 flight hours after doing the replacement required by paragraph (g)(1)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD for the remaining barrel nuts identified with a marking of LH7940T SPS 01. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement of all hardware at those locations is done. Do the inspection and replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(2) If three barrel nuts having no cracking are found, do the actions specified in paragraphs (g)(2)(i), (g)(2)(ii), and (g)(2)(iii) of this AD.

(i) Within 50 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 50 flight hours until the replacement specified in paragraph (g)(2)(ii) of this AD is done.

(ii) Within 100 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, replace all hardware for one affected barrel nut at the outboard location, on the side with two affected barrel nuts, in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used. Replacing the barrel nut on the outboard location terminates the requirement to do the repetitive inspections specified in paragraph (g)(2)(i) of this AD.

(iii) Within 100 flight hours after doing the replacement required by paragraph (g)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD for the remaining barrel nuts identified with a marking of LH7940T SPS 01. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement of all hardware at those locations is done. Do the inspection and replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(3) If two barrel nuts having no cracking are found and both nuts are on the same side, do the actions specified in paragraphs (g)(3)(i), (g)(3)(ii), and (g)(3)(iii) of this AD.

(i) Within 100 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement specified in paragraph (g)(3)(ii) of this AD is done.

(ii) Within 500 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, replace all hardware for one affected barrel nut at the outboard location that has two affected barrel nuts in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used. Replacing the barrel nut on the outboard location terminates the requirement to do the repetitive inspections specified in paragraph (g)(3)(i) of this AD.

(iii) Within 100 flight hours after doing the replacement required by paragraph (g)(3)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD for the remaining barrel nut identified with a marking of LH7940T SPS 01. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement of all hardware at that location is done. Do the inspection and replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(4) If two barrel nuts having no cracking are found and are on opposite sides, within 100 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement of all hardware at those locations is done. Do the inspection and replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

(5) If one barrel nut having no cracking is found, within 100 flight hours after doing the inspection required by paragraph (f)(2)(ii) of this AD, repeat the inspection specified in paragraph (f)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 100 flight hours until the replacement of all hardware at that location is done. Do the inspection and replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Revision B, dated March 6, 2008. As of the effective date of this AD, Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, must be used.

Actions Accomplished According to Previous Issue of Alert Service Bulletin

(h) Actions accomplished before February 13, 2008, in accordance with Bombardier Alert Service Bulletin A84–57–19, dated February 1, 2008, are acceptable for compliance with the corresponding actions specified in this AD.

Actions Accomplished According to Bombardier Alert Service Bulletin A84–57–18

(i) For airplanes on which the actions specified in Bombardier Alert Service Bulletin A84–57–18, dated January 16, 2008, were accomplished before February 13, 2008, and on which no barrel nuts were found that were identified with a marking of LH7940T SPS 01: No further action is required by this AD.

Parts Installation

(j) As of February 13, 2008, no person may install a barrel nut, part number DSC228–16, identified with a marking of LH7940T SPS 01, on any airplane.

New Requirement of This AD

Replacement of All Affected Barrel Nuts

(k) For airplanes on which barrel nuts are inspected in accordance with paragraph (g)(1)(iii), (g)(2)(iii), (g)(3)(iii), (g)(4), or (g)(5) of this AD: Within 3,000 flight hours after the effective date of this AD, replace all hardware for all remaining barrel nuts, part number DSC228–16, identified with a marking of LH7940T SPS 01. Do the replacement in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008. Replacement of all hardware for all affected barrel nuts constitutes terminating action for the repetitive inspections of this AD.

(l) For airplanes on which hardware for the barrel nut was replaced in accordance with Bombardier Alert Service Bulletin A84–57–19, dated February 1, 2008; or Revision A, dated February 6, 2008: Within 3,000 flight hours after the effective date of this AD, apply F13, Type 2 corrosion inhibiting compound to the affected bolts and barrel nuts in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008; except if it can be conclusively determined from a review of airplane maintenance records that F13, Type 2 corrosion inhibiting compound was applied to the affected bolts and barrel nuts, then no further action is required by this paragraph.

Special Flight Permit

(m) Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), may be issued to operate the airplane to a location where the requirements of this AD can be accomplished, but concurrence by the Manager, New York Aircraft Certification Office (ACO), FAA, is

required prior to issuance of the special flight permit. Before using any approved special flight permits, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO. Special flight permits may be permitted provided that the conditions specified in paragraphs (m)(1), (m)(2), (m)(3), (m)(4), and (m)(5) of this AD are met.

(1) Both the right-hand side and left-hand side of the airplane must have at least one barrel nut that is not within the suspect batch (i.e., barrel nut is not identified with a marking of LH7940T SPS 01). The barrel nuts that are not within the suspect batch must be in good working condition (i.e., no cracking of the barrel nut).

(2) No passengers and no cargo are onboard.

(3) Airplane must operate in fair weather conditions with a low risk of turbulence.

(4) Airplane must operate with reduced airspeed. For further information, contact Bombardier, Q Series 24 Hour Service Customer Response Center, at: Telephone 1–416–375–4000; fax 1–416–375–4539; E-mail: *thd.qseries@aero.bombardier.com.*

(5) All of the conditions specified in paragraphs (m)(1), (m)(2), (m)(3), and (m)(4) of this AD are on a case-by-case basis. Contact your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO, for assistance.

Alternative Methods of Compliance (AMOCs)

(n)(1) The Manager, New York ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Pong Lee, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7324; fax (516) 794–5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(o) Canadian airworthiness directive CF–2008–11R1, dated May 9, 2008, also addresses the subject of the AD.

Material Incorporated by Reference

(p) You must use Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008; or Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A84–57–19, Revision B, dated March 6, 2008, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On February 13, 2008 (73 FR 8187, February 13, 2008), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A84–57–19, Revision A, dated February 6, 2008.

(3) Contact Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada, for a copy of this service information. You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–19718 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0672; Directorate Identifier 2008–NM–032–AD; Amendment 39–15660; AD 2008–18–03]

RIN 2120–AA64

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

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

ACTION: Final rule.

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

During manufacturing of A330/A340 aircraft framework, cracks have been found on Frame (FR) 12, left (LH) and right (RH) sides. It has been confirmed that a defect of the FR12 forming tool press is the root cause of the cracks.

If undetected such damage could affect, after propagation, the structural integrity of the aircraft.

* * * * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective October 14, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 14, 2008.

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

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on June 24, 2008 (73 FR 35595). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

During manufacturing of A330/A340 aircraft framework, cracks have been found on Frame (FR) 12, left (LH) and right (RH) sides. It has been confirmed that a defect of the FR12 forming tool press is the root cause of the cracks.

If undetected such damage could affect, after propagation, the structural integrity of the aircraft.

In order to permit an early detection and repair of cracks on FR12, LH and RH sides, this Airworthiness Directive (AD) mandates a one time High Frequency Eddy Current (HFEC) inspection of FR12.

Corrective actions include, for certain findings, contacting Airbus for repair instructions and doing the repair; repairing cracking (i.e., installing a new splice); and applying new protective coatings and corrosion inhibitors. You may obtain further information by examining the MCAI in the AD docket.

Comments

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

Conclusion

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

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in

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

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

Costs of Compliance

We estimate that this AD will affect about 20 products of U.S. registry. We also estimate that it will take about 3 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Required parts will cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $4,800, or $240 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

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

Examining the AD Docket

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2008–18–03 Airbus: Amendment 39–15660. Docket No. FAA–2008–0672; Directorate Identifier 2008–NM–032–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 14, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330–200, A330–300, and A340–300 series airplanes; certificated in any category; all certified models, all manufacturing serial numbers (MSN) from MSN 0489 through 0722 inclusive, and MSN 0725, 0726, 0728, 0730, 0732, and 0734.

Subject

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

Reason

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

During manufacturing of A330/A340 aircraft framework, cracks have been found on Frame (FR) 12, left (LH) and right (RH) sides. It has been confirmed that a defect of the FR12 forming tool press is the root cause of the cracks.

If undetected such damage could affect, after propagation, the structural integrity of the aircraft.

In order to permit an early detection and repair of cracks on FR12, LH and RH sides, this Airworthiness Directive (AD) mandates a one time High Frequency Eddy Current (HFEC) inspection of FR12.

Corrective actions include, for certain findings, contacting Airbus for repair instructions and doing the repair; repairing cracking (i.e., installing a new splice); and applying new protective coatings and corrosion inhibitors.

Actions and Compliance

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

(1) Prior to the accumulation of 19,500 total flight cycles or within 3 months after the effective date of this AD, whichever occurs later: Perform a HFEC inspection at the LH and RH sides of frame 12, in accordance with the instructions defined in Airbus Mandatory Service Bulletin A330–53–3174 or A340–53–4177, both dated October 10, 2007, as applicable. If no cracking is found, no further action is required by this AD. Except as required by paragraph (f)(2) of this AD, if any cracking is found, before further flight, do the applicable corrective actions in accordance with the instructions of Airbus Mandatory Service Bulletin A330–53–3174 or A340–53–4177, as applicable.

(2) If any cracking is found that exceeds the limits specified in Airbus Mandatory Service Bulletin A330–53–3174 or A340–53–4177, both dated October 10, 2007, as applicable; or if any cracking is found during any HFEC inspection of the cut-out area; before further flight, contact Airbus for repair instructions and do the repair.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No difference.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Vladimir Ulyanov, Aerospace Engineer, International

Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

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

Related Information

(h) Refer to European Aviation Safety Agency (EASA) Airworthiness Directive 2007–0302, dated December 14, 2007; and Airbus Mandatory Service Bulletins A330–53–3174 and A340–53–4177, both dated October 10, 2007; for related information.

Material Incorporated by Reference

(i) You must use Airbus Mandatory Service Bulletin A330–53–3174, including Appendix 01, dated October 10, 2007; or Airbus Mandatory Service Bulletin A340–53–4177, including Appendix 01, dated October 10, 2007; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

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

Issued in Renton, Washington, on August 18, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–19720 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0407; Directorate Identifier 2008–NM–002–AD; Amendment 39–15662; AD 2008–18–05]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model 717–200 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain McDonnell Douglas Model 717–200 airplanes. This AD requires inspecting the drive assembly of the aft elevator standby loop of the elevator standby cable system for interference between the clevis and bolt of the bellcrank assembly, correct orientation of the pull-pull cable clevis bolt, and excessive freeplay of the bellcrank assembly bearing, and corrective actions if necessary. This AD also requires modifying the pull-pull cable clevis in the drive assembly of the aft elevator standby loop for certain airplanes. This AD results from a report of an aborted takeoff due to a control column disconnect. We are issuing this AD to prevent binding of the bolt that connects the cable 264A clevis to the bellcrank assembly against the adjacent (upper) clevis of the pull-pull cable assembly. This binding condition could result in slow airplane rotation or a control column disconnect during takeoff and a runway excursion if takeoff must be aborted.

DATES: This AD is effective October 14, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 14, 2008.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846; Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: David Rathfelder, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5229; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to certain McDonnell Douglas Model 717–200 airplanes. That NPRM was published in the **Federal Register** on April 7, 2008 (73 FR 18725). That NPRM proposed to require inspecting the drive assembly of the aft elevator standby loop for interference between the clevis and bolt of the bellcrank assembly, correct orientation of the pull-pull cable clevis bolt, and excessive freeplay of the bellcrank assembly bearing, and corrective actions if necessary. That NPRM also proposed to require modifying the pull-pull cable clevis in the drive assembly of the aft elevator standby loop for certain airplanes.

Comments

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

Request To Change Summary Section for Clarification

Boeing asks that the second sentence of the Summary section in the NPRM, which describes what is to be inspected, be changed as follows: ''This proposed AD would require inspecting the aft elevator standby loop drive assembly of the elevator standby cable system for interference between the clevis and bolt of this bellcrank assembly, correct orientation of the pull-pull cable clevis bolt, and excessive freeplay of the bellcrank assembly bearing, and corrective actions if necessary.'' Boeing states that this would more accurately describe the drive assembly being inspected since there are two drive assemblies in the elevator standby cable system.

We agree that the description in the Summary section of the AD should be clarified. Therefore, we have changed the Summary section and all other

relevant sections in the AD to meet the commenter's intent.

Requests To Extend Compliance Time

Midwest Airlines asks that the compliance time in the NPRM be changed to one of the following: ''Complete the inspection and modification within 27 months of the effective date of the AD,'' or ''Complete the inspection and modification within 3,000 flight hours or 27 months, whichever occurs later from the effective date of the AD.'' Midwest Airlines states that it currently has a utilization of 3,450 flight hours per year, and if the compliance time is not changed, it would require compliance for all its airplanes in less than one year. Midwest Airlines also states that it checked some of its airplanes for the interference and none was found.

Air Tran proposes that the inspection and clevis replacement specified in the NPRM be done concurrently at 27 months after the effective date of the AD, rather than the inspection being limited to 3,000 flight hours. Air Tran states that since similar access is required for both the inspection and clevis replacement, it is more practical to accomplish the clevis replacement at the same time as the inspection. Twenty-seven months aligns with the Model 717 maintenance program heavy maintenance visits, but 3,000 flight hours does not.

We agree to extend the compliance time for performing the inspection for the reasons provided by the commenters. We have determined that a compliance time of within 3,000 flight hours or 27 months after the effective date of the AD, whichever occurs later, is appropriate and will ensure an acceptable level of safety. We have changed paragraph (f)(1) of this AD accordingly. The compliance time for doing the clevis modification specified in paragraph (f)(2) of this AD remains the same. Changing the compliance time for the inspection provides the opportunity to do the inspection and modification at the same time.

Request To Change Cost Section

Midwest Airlines states that the work-hour estimate specified in the Costs of Compliance section of the NPRM is underestimated. Midwest Airlines notes that the NPRM specifies 1 work-hour for the inspection and the referenced service bulletin specifies 2.4 to 11.9 work hours. Midwest Airlines adds that the NPRM specifies 4 work-hours for the modification and the referenced service bulletin specifies 5.4 work-hours. Midwest Airlines believes the service bulletin is more accurate than the NPRM.

From this comment, we infer that Midwest Airlines would like us to increase the work-hour estimate given in the NPRM. We do not agree. The cost information below describes only the direct costs of the specific actions required by this AD. Based on the best data available, the manufacturer provided the number of work hours (1 for the inspection, 4 for the modification) necessary to do the required actions, as specified in the service bulletin. We recognize that, in doing the actions required by an AD, operators might incur incidental costs in addition to the direct costs. The cost analysis in AD rulemaking actions, however, typically does not include incidental costs such as the time required to gain access and close up, time necessary for planning, or time necessitated by other administrative actions. Those incidental costs, which might vary significantly among operators, are almost impossible to calculate. We have made no change to the AD in this regard.

Conclusion

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

Costs of Compliance

We estimate that this AD will affect 123 airplanes of U.S. registry.

It will take about 1 work-hour per product to do the inspection. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of the inspection required by this AD to the U.S. operators to be $9,840, or $80 per product.

It will take about 4 work-hours per product to do the modification. Required parts will cost about $163 per product. Based on these figures, we estimate the cost of the modification required by this AD to the U.S. operators to be $59,409, or $483 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2008–18–05 McDonnell Douglas: Amendment 39–15662. Docket No. FAA–2008–0407; Directorate Identifier 2008–NM–002–AD.

Effective Date

(a) This airworthiness directive (AD) is effective October 14, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to McDonnell Douglas Model 717–200 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 717–27A0039, dated December 6, 2007.

Unsafe Condition

(d) This AD results from a report of an aborted takeoff due to a control column disconnect. We are issuing this AD to prevent binding of the bolt that connects the cable 264A clevis to the bellcrank assembly against the adjacent (upper) clevis of the pull-pull cable assembly. This binding condition could result in slow airplane rotation or a control column disconnect during takeoff and a runway excursion if takeoff must be aborted.

Compliance

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

Inspection/Corrective Actions

(f) Do the applicable actions specified in paragraphs (f)(1) and (f)(2) of this AD at the time specified, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 717–27A0039, dated December 6, 2007.

(1) For all airplanes: Do a general visual inspection of the drive assembly of the aft elevator standby loop of the elevator standby cable system for interference between the clevis and bolt of the bellcrank assembly, correct orientation of the pull-pull cable clevis bolt, and excessive freeplay of the bellcrank assembly bearing. Do the inspection within 3,000 flight hours or 27 months after the effective date of this AD, whichever occurs later. Do all applicable corrective actions before further flight.

(2) For airplanes identified in the service bulletin as Group 1, Configuration 1: Modify the pull-pull cable clevis in the drive assembly of the aft elevator standby loop of the elevator standby cable system. Do the modification at the applicable time specified in paragraph 1.E., ''Compliance,'' of the service bulletin; except, where the service bulletin specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, ATTN: David Rathfelder, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5229; fax (562) 627–5210; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

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

Material Incorporated by Reference

(h) You must use Boeing Alert Service Bulletin 717–27A0039, dated December 6, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846; Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

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

Issued in Renton, Washington, on August 18, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–19721 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0562; Directorate Identifier 2008–NM–010–AD; Amendment 39–15658; AD 2008–18–01]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 Airplanes

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

ACTION: Final rule.

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

It has been found cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective October 14, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 14, 2008.

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

FOR FURTHER INFORMATION CONTACT: Kenny Kaulia, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2848; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on May 20, 2008 (73 FR 29085). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

It has been found cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

Corrective actions include inspecting for the presence of pressure equalization valves and, if necessary, installing pressure equalization valves. You may obtain further information by examining the MCAI in the AD docket.

Comments

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

Conclusion

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

Differences Between This AD and the MCAI or Service Information

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

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

Costs of Compliance

We estimate that this AD will affect about 101 products of U.S. registry. We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $8,080, or $80 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

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

Examining the AD Docket

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2008–18–01 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–15658. Docket No. FAA–2008–0562; Directorate Identifier 2008–NM–010–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 14, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to EMBRAER Model ERJ 170–100 LR, –100 STD, –100 SE, –100 SU, –200 LR, –200 STD, and –200 SU airplanes, having serial numbers (S/N) 17000002, 17000004 through 17000013, and 17000015 through 17000154; and Model ERJ 190–100 STD, –100 LR, –100 IGW, –100 ECJ, –200 STD, –200 LR, and –200 IGW airplanes, having S/N 19000002, 19000004, and 19000006 through 19000060; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 21: Air Conditioning.

Reason

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

It has been found cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

Corrective actions include inspecting for the presence of pressure equalization valves and, if necessary, installing pressure equalization valves.

Actions and Compliance

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

(1) Within 500 flight hours after the effective date of this AD, perform a general visual inspection on the left-hand bulkhead blowout panel of both the forward and aft cargo compartments to determine whether the pressure equalization valves, part number (P/N) 120–48865–003, are installed. If both pressure equalization valves are installed in their respective blowout panels, no additional action is required by this AD.

(2) If any valve is not installed, within 700 flight hours after the effective date of this AD, install valve P/N 120–48865–003, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170–21–0032 or 190–21–0019, both dated August 10, 2007; as applicable.

Note 1: For the purpose of this AD, a general visual inspection (GVI) is: ''A visual examination of an interior or exterior area, installation or assembly to detect obvious damage, failure or irregularity. This level of inspection is made from within touching distance, unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight or drop-light, and may require removal or opening of access panels or doors. Stands, ladders or platforms may be required to gain proximity to the area being checked.''

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Kenny Kaulia, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate,

FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2848; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

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

Related Information

(h) Refer to MCAI Brazilian Airworthiness Directives 2007–11–01 and 2007–11–02, both effective December 12, 2007; and EMBRAER Service Bulletins 170–21–0032 and 190–21–0019, both dated August 10, 2007; for related information.

Material Incorporated by Reference

(i) You must use EMBRAER Service Bulletin 170–21–0032, dated August 10, 2007; or EMBRAER Service Bulletin 190–21–0019, dated August 10, 2007; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil.

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

Issued in Renton, Washington, on August 18, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–19850 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–0036; Directorate Identifier 2007–NE–22–AD; Amendment 39–15636; AD 2008–16–18]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211–524 Series Turbofan Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2008–16–18. That AD applies to Rolls-Royce (RR) RB211–524 series turbofan engines with certain high pressure (HP) turbine disks installed. That AD was published in the **Federal Register** on August 11, 2008 (73 FR 46550). Paragraph (c) in the regulatory section is incorrect. This document corrects that paragraph. In all other respects, the original document remains the same.

DATES: *Effective Date:* Effective September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e–mail: *jason.yang@faa.gov*; telephone (781) 238–7747; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: On August 11, 2008 (73 FR 46550), we published a final rule AD, FR Doc. E8–18102, in the **Federal Register**. That AD applies to RR RB211–524 series turbofan engines. We need to make the following correction:

§ 39.13 [Corrected]

On page 46551, in the first column, in the Regulatory Section, in the Applicability paragraph (c), in the second line, ''with certain high pressure (HP) turbine discs installed'' is corrected to read ''with high pressure (HP) turbine discs, part numbers (P/Ns)-serial numbers (SNs) FK24651–LAQDY6061 and –LDRCZ10453 to –LDRCZ10720, and –LQDY9903, and –LQDY9924, FK24790–CRCZ6 to –CRCZ25 and –LDRCZ10717 to –LDRCZ14022, UL23166–LQDY6516 to –LQDY8718, UL24561–LQDY6389 to –LQDY6438, UL24994–LQDY6405 to –LQDY8727, UL29472–LAQDY6013 to –LAQDY6092 and –LDRCZ10029 to –LDRCZ10821 and –LDRCZ6000 to –LDRCZ6060 and –LQDY6592 to –LQDY9993, UL29473–CRCZ24 to –CRCZ25 and –CZ12135 to –CZ12333 and –LAQDY6010 to –LAQDY6088 and –LDRCZ10003 to –LDRCZ15372 and –LDRCZ6001 to –LDRCZ9995 and –LQDY10001 and –LQDY9606 to –LQDY9989, installed''.

Issued in Burlington, Massachusetts, on August 28, 2008.

Marc Bouthillier,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E8–20498 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

21 CFR Parts 16 and 1240

[Docket No. FDA–2003–N–0427] (formerly Docket No. 2003N–0400)

Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCY: Food and Drug Administration (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing its regulation that established restrictions on the capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals. We are removing the restrictions because we believe they are no longer needed to prevent the further introduction, transmission, or spread of monkeypox, a communicable and potentially fatal disease, in the United States.

DATES: Effective September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Preparedness (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

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I. What Is Monkeypox, and How Did It Spread in the United States?

Monkeypox is a sporadic, zoonotic, viral disease that occurs primarily in the rain forest countries in central and west Africa. (A zoonotic disease is a disease of animals that can be transmitted to humans under natural conditions.) The illness was first noted in a monkey in 1958 (which explains its name), but, in Africa, serologic evidence of monkeypox infection has been found in many other species, including some species of primates, rodents, and lagomorphs. Lagomorphs include animals such as rabbits. African rodents are considered to be the most likely natural host of the monkeypox virus (Ref. 1). In Africa, however, direct viral evidence of monkeypox has been found in only one native African rodent species (a rope squirrel), but this may be due to the limited scope of the ecologic studies that have been done in Africa (Ref. 1).

In humans, monkeypox is marked by rashes that are similar to those seen in smallpox; other signs and symptoms include a temperature at or above 99.3 degrees, chills and/or sweats, headache, backache, lymphadenopathy (a disease of the lymph nodes), sore throat, cough, and shortness of breath (Ref. 2). The disease's incubation period in humans is approximately 12 days (Ref. 3). In Africa, monkeypox has a mortality (death) rate in humans ranging from 1 to 10 percent of the people who become infected, although higher mortality rates have been seen.

In May and June of 2003, public health officials identified an outbreak of human monkeypox in the United States. Epidemiological and traceback investigations by State and Federal agencies revealed that the patients became infected primarily as a result of contact with prairie dogs that had contracted monkeypox from diseased African rodents. The investigations indicated that a Texas animal distributor imported a shipment of approximately 800 small mammals from Ghana on April 9, 2003. This shipment contained 762 African rodents, including rope squirrels (*Funiscuirus* sp.), tree squirrels (*Heliosciurus* sp.), Gambian giant pouched rats (*Cricetomys* sp.), brushtail porcupines (*Atherurus* sp.), dormice (*Graphiurus* sp.), and striped mice (*Hybomys* sp.). Some of these African animals were infected with monkeypox, and laboratory testing confirmed the presence of monkeypox in several rodent species, including two Gambian giant pouched rats, nine dormice, and three rope squirrels (Ref. 23). Of the 762 rodents from the original shipment, 584 were traced to distributors in 6 states. A total of 178 African rodents could not be traced beyond the point of entry in Texas because records were not available (Ref. 4).

Some African rodents made their way to an animal distributor in Illinois who also sold prairie dogs (Ref. 5). The Illinois animal distributor had approximately 200 prairie dogs. Thirty-nine of these prairie dogs, along with one Gambian giant pouched rat, went to another animal distributor in Wisconsin in early May, 2003; it was at this time that several prairie dogs appeared to be ill, and several of the animals died (Ref. 5). By late May, the first human cases began to appear in Wisconsin (including the Wisconsin animal distributor), with other human cases appearing later in Kansas, Missouri, Illinois, Indiana, and Ohio (Refs. 5 and 6).

Of the 200 prairie dogs that were at the Illinois animal distributor, only 93 were able to be traced during the traceback investigation (Ref. 4).

The 2003 monkeypox outbreak in the United States eventually resulted in 72 human cases, with 37 of those cases being laboratory-confirmed (Ref. 7). Most patients had direct or close contact with prairie dogs. For example, 28 children at an Indiana day care center were exposed to 2 prairie dogs that later became ill and died. Twelve of these exposed children reported handling or petting the prairie dogs, and seven of these children later became ill with symptoms that were consistent with monkeypox infection (Ref. 7). In Wisconsin, more than half of the human monkeypox cases occurred through occupational exposure to infected prairie dogs, with veterinary staff being at greater risk of acquiring monkeypox than pet store employees (Ref. 21). The human cases in the United States included children as young as 3 years old, and 19 people were hospitalized, although some were hospitalized primarily for isolation purposes (Ref. 6). The initial signs or symptoms seen in some patients included skin lesions or fever with drenching sweats and severe chills (Ref. 5). Other signs and symptoms seen most often included:

- Headache;
- Persistent cough;
- Lymphadenopathy; and
- Sore throat (Ref. 5).

Less frequent signs and symptoms included:

- Pharyngitis;
- Tonsillar hypertrophy;
- Tonsillar erosions;
- Malaise;
- Mild chest tightness;
- Diarrhea;
- Myalgias;
- Back pain;
- Nasal congestion;
- Blephartis; and
- Nausea (Ref. 5).

In general, the human cases in the United States were milder than those seen in Africa (Ref. 6), and patients who had been vaccinated against smallpox appeared to have milder cases compared to those who had not been vaccinated against smallpox. However, two children suffered serious clinical illnesses. One child had severe encephalitis that improved during a 14-day hospital stay, and another child had pox lesions on many parts of her body, including lesions inside her mouth and throat which created difficulty in breathing and swallowing (Refs. 6, 9, and 19). At least 5 patients (3 adults and 2 children) had temperatures greater than or equal to 38.3 °C (100.94 °F) and rashes comprised of 100 or more lesions (Ref. 9). One adult patient remained symptomatic for approximately 5 months; the patient became asymptomatic only after having a corneal transplant (Ref. 9).

II. How Did We Respond to the Monkeypox Outbreak?

On June 11, 2003, the Director of the Centers for Disease Control and Prevention (CDC) and the Commissioner of Food and Drugs, under 42 CFR 70.2 and 21 CFR 1240.30 respectively, issued a joint order (Refs. 10 and 11) prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (*Cynomys* sp.);
- Tree squirrels (*Heliosciurus* sp.);
- Rope squirrels (*Funisciurus* sp.);
- Dormice (*Graphiurus* sp.);
- Gambian giant pouched rats (*Cricetomys* sp.);
- Brush-tailed porcupines (*Atherurus* sp.), and
- Striped mice (*Hybomys* sp.).

The June 11, 2003, order did not apply to the transport of listed animals to veterinarians or animal control

officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities. In addition, under 42 CFR 71.32(b), CDC implemented an immediate embargo on the importation of all rodents (order *Rodentia*) from Africa.

FDA and CDC issued the June 11, 2003, order to address quickly what was then a new and rapidly developing monkeypox outbreak (Ref. 11). As the two agencies became more experienced with the order and more knowledgeable about the monkeypox outbreak, it became apparent that we and CDC needed a regulatory approach to prevent the monkeypox virus from becoming established and spreading in the United States and to modify the June 11, 2003, order, such as creating exemption procedures to accommodate special circumstances. Consequently, on November 4, 2003 (68 FR 62353), FDA and CDC issued an interim final rule that superseded the June 11, 2003, order. The interim final rule created two complementary regulations. First, with respect to certain animals that are in the United States, the interim final rule added 21 CFR 1240.63 entitled ''African rodents and other animals that may carry the monkeypox virus.'' Second, for African rodents that are being imported or offered for import to the United States, the interim final rule added 42 CFR 71.56 that is also entitled ''African rodents and other animals that may carry the monkeypox virus.'' We are responsible for 21 CFR 1240.63, and CDC is responsible for 42 CFR 71.56; both sets of regulations are intended to prevent the further introduction, establishment, and spread of the monkeypox virus in the United States.

We also indicated that we would revoke or amend, as warranted, all or parts of 21 CFR 1240.63 if we concluded that monkeypox is eradicated or adequately controlled so that the virus does not become established in the United States (see 68 FR at 62359).

We issued the interim final rule under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). Section 361 of the PHS Act gives the Secretary of Health and Human Services (the Secretary) the authority to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State.

III. What Other Actions Did the Department of Health and Human Services Take?

A. Why Did the Interim Final Rule Continue After January 20, 2004?

The preamble to the interim final rule stated that:

> Monkeypox is endemic in parts of Africa. Therefore, we do not anticipate revoking the prohibition on import of African rodents and any other animals that the Director of CDC has specified under 42 CFR § 71.56(a)(1)(i). However, FDA will revoke or amend, as warranted, all or parts of 21 CFR § 1240.63 if FDA concludes that monkeypox is eradicated or adequately controlled so that the virus does not become established in the United States. FDA's decision would depend on scientific principles for controlling zoonotic diseases. For example, if the incubation period is known, then it would be prudent to continue the restrictions for a time period that is double the incubation period to ensure that there is little further risk of infection or restarting the monkeypox outbreak. CDC tests on some animals involved in the original April 9, 2003, shipment from Ghana suggest that, insofar as dormice are concerned, the incubation period may be as long as 2.5 months. If FDA rounds this time frame up to 3 months, and then doubles the incubation period, there would appear to be little further risk of infection after 6 months had passed with no further evidence of monkeypox identified, and FDA would be able to take actions to revoke or amend 21 CFR § 1240.63. The last infected animal from the April 9, 2003, shipment that died from monkeypox died on July 20, 2003. There have been no identified monkeypox cases in animals or people in the United States since that date. If no further monkeypox cases are identified in the United States, and if there is no new information warranting an extension of the 6-month time period, FDA intends to revoke or amend 21 CFR § 1240.63 as early as January 20, 2004, which will be six months after July 20, 2003. At that time, if FDA decided to revoke or amend 21 CFR § 1240.63, it would publish an appropriate document (such as a proposed rule or direct final rule) in the **Federal Register**. FDA invites comments on this approach.

(Id. at page 62359.) However, the preamble to the interim final rule also cautioned that:

> We emphasize that any possible revocation or amendment of 21 CFR § 1240.63 may also depend on new data or new developments. For example, various animal studies are being conducted to learn more about the incubation period and transmission dynamics of monkeypox. If those studies suggest that the period for incubation and transmission may be longer than 2.5 months, FDA could decide to recalculate the date on which it might revoke or amend 21 CFR § 1240.63. Studies are also underway to determine whether certain species that may be infected with the virus, but not display any symptoms, can infect other species. To illustrate how the virus could spread from an asymptomatic animal, assume that an animal can carry the monkeypox virus, but that the animal does not develop monkeypox. If that animal later comes into contact with prairie dogs, a species which is already known to be susceptible to monkeypox, then the prairie dogs could become infected, and another monkeypox outbreak in prairie dogs could erupt. Again, if the CDC studies suggest that species can be asymptomatic, but still infectious, those results could cause FDA to recalculate the date on which it could revoke or amend 21 CFR § 1240.63.

(Id.)

After the interim final rule's publication in the **Federal Register** on November 4, 2003, CDC notified us that it had test information that warranted our continued application and enforcement of 21 CFR 1240.63. This information confirmed monkeypox virus infection in several prairie dogs and in a few animals from other species, including a Gambian giant pouched rat, dormice, rope squirrels, a ground hog, a South American opossum, and a chinchilla. Some of these infections were subclinical (the animal was infected with the virus, but did not appear to be ill). Some of this preliminary information subsequently appeared in peer-reviewed scientific journal articles, and, in a **Federal Register** notice dated February 21, 2007 (72 FR 7825), we announced the addition of those articles and other recent journal articles to the docket. However, follow-up investigations confirmed that the human monkeypox cases in the United States were not associated with exposure to any animals except prairie dogs.

CDC also was monitoring the progress of a human case where a patient had developed monkeypox in late June 2003, but still had symptoms 5 months later. Conjunctival swabs from this patient were positive (following polymerase chain reaction (PCR) analysis) at 139 days after onset and culture positive at 126 days after onset. This patient eventually required a corneal transplant (see Ref. 9 which discusses this case briefly).

We also note that, when we wrote the interim final rule, efforts were continuing to track down animals from the original African shipment as well as prairie dogs from the Illinois distributor. Ultimately, over 170 African rodents from that shipment and 103 prairie dogs from the Illinois distributor were never recovered or located.

B. Were the New Data Available to the Public?

In the **Federal Register** of April 14, 2004, the Department of Health and Human Services published a notice announcing that the Secretary's Council on Public Health Preparedness

(Secretary's Council) would hold a public meeting where one topic would be ''Transport of Possibly Infected Exotic Animals'' (see 69 FR 19854 (April 14, 2004)). The Secretary's Council invited FDA and CDC to make presentations regarding the interim final rule. FDA made a presentation to the Secretary's Council seeking its advice on assessing the risk of monkeypox in the United States so that we could determine the appropriate way to manage that risk. CDC presented information concerning the new data, thus making the data publicly available. The Secretary's Council did not assess the risk of monkeypox; it recommended instead that the interim final rule's restrictions on prairie dogs and certain African rodents remain in place, although it also recommended that we make minor clarifications or changes to the rule so that prairie dog owners could take their animals to receive veterinary care and to transport their animals in certain situations. The Secretary's Council did not issue its recommendations in writing.

C. Is There a Risk That Monkeypox Still Exists in the United States?

From mid-2004 through 2007, more information regarding the 2003 monkeypox outbreak appeared in the scientific and medical literature. For example, two scientific articles demonstrated that the monkeypox virus easily infected prairie dogs and that infection in prairie dogs could occur through contact or through inhalation (Refs. 13 and 17). Another article described the laboratory evaluation of animals associated with the monkeypox outbreak; the authors examined tissue samples from 249 animals of 26 different species and found the monkeypox virus in 33 animals (Ref. 23). These animals included three rope squirrels, two Gambian giant pouched rats, and nine dormice from the shipment of African rodents (Ref. 23). Additionally, 14 of 20 prairie dogs tested were PCR positive for the monkeypox virus deoxyribonucleic acid (DNA), and infectious virus was recovered from 9 of 11 prairie dogs (Ref. 23). In general, prairie dogs also had higher levels of monkeypox virus or monkeypox virus DNA than other animal species (Ref. 23). The authors also found monkeypox virus DNA in tissues of other animal species housed at the Illinois establishment; this suggested that monkeypox could infect several animal species (Ref. 23). The article also described the limited, live-trapping of wild animals that the United States Department of Agriculture's Wildlife Service and the United States Geologic Survey's National Wildlife Health Center completed after the United States monkeypox outbreak. Trapping of 201 animals occurred at sites located near where six human monkeypox cases (and associated captive prairie dogs) in Wisconsin occurred. No evidence of orthopox virus infection in any of these animals was detected. (The term ''orthopox virus'' refers to a genus (a term used in biology to denote a type or group that is above that of a species) of poxviruses. Examples of orthopox viruses include monkeypox virus, cowpox virus, and the variola virus; the variola virus causes smallpox.) The Illinois Wildlife Services program conducted further trapping studies in Illinois at three locations linked by trash disposal routes to the Illinois animal distributor. Forty-three animals were trapped, and all were negative for evidence of orthopox virus infection (Ref. 23).

Other articles (Refs. 14, 15, and 9) shed more light as to why the 2003 outbreak in the United States was not as deadly as those seen in Africa; for example, there are two different strains (or ''clades'') of the monkeypox virus, and the virus that appeared in the United States was representative of the less virulent (and less transmissible between humans) strain insofar as humans are concerned (Refs. 14 and 20). The risk of infection in humans correlated with the type of exposure to infected prairie dogs, and most human cases in the United States were associated with direct contact to (specifically the handling of) infected prairie dogs (Refs. 16 and 22). Children (persons under 18 years old) who were infected were more likely to be hospitalized in intensive care compared to infected adults (Ref. 9). Additionally, while some adults had received smallpox vaccinations before 1972, it is unclear as to whether childhood smallpox vaccinations offer durable protection against monkeypox. Some articles indicated that there did not appear to be significant differences in serious clinical observations or complications between vaccinated and unvaccinated adults (Ref. 9 and 20), yet another suggested that an individual's history of smallpox vaccination might protect against monkeypox illness (Ref. 21). In brief, the recent publications validate and reinforce the facts that:

- Prairie dogs are easily infected with the monkeypox virus, and infected prairie dogs have higher levels of monkeypox virus than other infected animals;
- Human cases in the United States were linked to contact with infected prairie dogs; and
- Monkeypox is a serious disease, particularly in children, but the virus implicated in the United States was representative of the less virulent and less transmissible between humans strain.

More significantly, one recent article assessed the risk for monkeypox associated with domestic trade in certain animal species in the United States (Ref. 18). The authors evaluated the data and uncertainties concerning monkeypox and its potential spread to animal and human populations in the United States and characterized in a qualitative analysis the probability of harm based on that data. They concluded that the risk for further domestically acquired human infections is low with the restrictions that FDA and CDC had established. The authors noted that there have been no new cases in humans or animals in the United States since the outbreak, despite the likelihood that some surviving infected animals may have been kept alive by pet owners or dealers. However, there have been no prospective surveillance activities that would fully address this question.

IV. Given Recent Evidence, Is FDA Action Still Necessary?

A. Are the Measures of the Interim Final Rule Needed Now to Prevent Disease Spread?

As we explained in the preamble to the interim final rule, we issued the interim final rule under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264) (see 68 FR at 62360) to prevent the spread of communicable disease. Section 361 of the PHS Act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see *State of Louisiana* v. *Mathews*, 427 F. Supp. 174 (E.D. La. 1977)).

We have invoked section 361 of the PHS Act to regulate various activities and articles. For example, we have invoked this authority to prevent the transmission of communicable disease through certain shellfish, turtles, certain birds, and human tissue intended for transplantation (see 21 CFR 1240.60 (molluscan shellfish), 1240.62 (turtles), 1240.65 (psittacine birds), and 1270.1 through 1270.43 (human tissue)).

Our regulations, at 21 CFR 1240.30, provide further insight as to when we will use our communicable disease

authority. The regulation, in relevant part, states that:

> Whenever the Commissioner of Food and Drugs determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he may take such measures to prevent such spread of the diseases as he deems reasonably necessary * * *

Thus, when we issued the June 11, 2003, order and later issued the interim final rule, we acted because we determined that measures taken by State health authorities, in 2003, were insufficient to prevent the spread of monkeypox. We took those actions because infected and potentially infected animals were crossing State lines, and human cases were appearing in several States; the multi-state impact, as well as the then-rapidly developing outbreak, indicated that measures taken by individual States would be insufficient to prevent the spread of monkeypox.

The risk assessment published in 2006, however, suggests that the risk of further monkeypox transmission from the original events of 2003, particularly to humans, in the United States is low. Consequently, based on that low risk, we believe that the import controls of CDC's interim final rule in 42 CFR 71.56 and routine State surveillance and disease prevention measures should be sufficient to prevent further human and animal monkeypox cases. Therefore, we have concluded that the domestic controls in 21 CFR 1240.63 are no longer necessary, and we are removing our regulation.

Please note that this revocation pertains solely to FDA's provisions at 21 CFR 1240.63; the requirements imposed by the CDC at 42 CFR 71.56 remain in effect.

B. How Many Comments Did We Receive?

The interim final rule provided an opportunity for public comment; this comment period expired on January 20, 2004. We received over 570 comments on the interim final rule. We received comments from State government agencies or departments, zoos, zoological associations, animal interest groups, animal breeders, animal vendors, and individuals, including foreign citizens. The comments reflected a wide array of differing and sometimes conflicting opinions. For example, most, but not all, State agencies supported the rule. Most State agencies appreciated Federal efforts in responding to the monkeypox outbreak, but one State agency criticized the rule as interfering with the State's wildlife management obligations, and another State agency commented that it, rather than FDA, should operate a permit system that would enable certain animals to move within a State. As another example, many individuals commenting on the rule either captured, sold, owned, or wanted to own prairie dogs and objected strongly to the rule's impact on the prairie dog trade and to continuing the rule. In contrast, a few individuals supported the rule and advocated more stringent measures regarding the pet trade, including animals that the interim final rule did not address.

The comments also varied in their complexity and familiarity with the rule. For example, the American Zoo and Aquarium Association (AZA) recommended a specific change in the rule for AZA-accredited zoological parks because of the quarantine protocols used by AZA-accredited zoos; the AZA included its detailed accreditation standards as part of its comment. In contrast, many comments simply expressed their strong objections to the rule, particularly as it applied to prairie dogs, without explaining the reasons for their objections, discussing any specific regulatory provision, or suggesting any alternative approaches. Some comments advocated defiance or violations of the rule. Several comments denied that monkeypox is a serious disease, although they offered no evidence to contradict the scientific or medical reference we had cited. Other comments criticized the rule or FDA harshly, yet some criticisms pertained to issues that were not in the interim final rule or to actions, statements, or positions that were mistakenly attributed to us. For example, some comments accused us of killing or conspiring to kill prairie dogs. Virtually none of these comments mentioned any other animal covered by the interim final rule, and none offered any evidence to support their accusations.

Additionally, we received over 120 more comments on a notice that appeared in the **Federal Register** on February 19, 2004 (69 FR 7752). The notice was a routine opportunity for public comment on the information collection provisions in a rule pursuant to the Paperwork Reduction Act of 1995. In this particular case, the notice pertained to the information we were requiring from persons who wanted our permission to capture, offer to capture, transport, offer to transport, sell, barter, or exchange, or offer to sell, barter, or exchange, distribute, offer to distribute, and/or release into the environment any animals covered by the rule. Specifically, the notice sought comment on the numerical estimates pertaining to the permit information, such as the estimated number of persons who would request a permit, the number of hours they would spend in preparing a permit request, the frequency at which permit requests would be submitted, etc. Most comments either interpreted or treated the notice as either a new opportunity to comment on the interim final rule or as finalizing the interim final rule. As a result, almost all comments submitted in response to the Paperwork Reduction Act notice focused on whether the interim final rule should remain in effect and did not address the collection of information under the Paperwork Reduction Act or any of our Paperwork Reduction Act estimates. Even though most comments submitted in response to the February 19, 2004, notice were not relevant to the Paperwork Reduction Act and were submitted months after the interim final rule's comment period had expired, we considered those comments in addition to the comments that were submitted in response to the interim final rule.

Finally, we received seven comments in response to a **Federal Register** notice which we published on February 21, 2007 (72 FR 7825). The notice added new information, primarily in the form of peer-reviewed scientific literature, to the administrative record, and we invited comment on the information being added. Of the seven comments, only one addressed a specific new reference. (The comment challenged the risk assessment article discussed earlier in section III.C of this document. The comment opined that the article ''may underestimate the potential disease transmission risk associated with wild-caught prairie dogs,'' but did not challenge the authors' methodology or the authors' conclusion that the risk of monkeypox associated with the 2003 introduction of the virus into the United States was low. Rather, the comment noted a risk of transfer or importation of infectious pathogens risk remains due to illegal importation of animals, as well as the risk that domestic wild animals, particularly prairie dogs, may be a source for diseases other than monkeypox, such as plague and tularemia. The comment argued that there is no way to estimate the degree of illegal importation of African rodents or the legal importation of other potentially infected species. We note that the article does address each of these points.) Most comments discussed issues that were outside the scope of the **Federal Register** notice of February 21, 2007, such as urging FDA to retain its regulation, discussing the invasive

species potential of a Gambian Giant Pouched Rat population located in Florida, discussing plague and tularemia in prairie dogs, or discussing the pet trade, zoonotic diseases generally, or gaps in Federal authority.

Given our decision to remove the regulation based on the current evidence and circumstances, we will not respond in detail to all of the comments that opposed the rule. However, we would like to clarify a few points as follows:

• Many individuals believed that the rule was unfair because the Federal Government did not act against other animals that are capable of transmitting disease to humans. These individuals often argued that the Federal Government did not ''ban'' cows despite bovine spongiform encephalopathy (BSE, or ''mad cow disease'') disease; dogs despite rabies; birds due to West Nile virus; or other animals associated with zoonotic diseases. Some claimed that we were discriminating against prairie dogs because they believed a rabbit had been infected with monkeypox, yet we did not include rabbits in the rule.

As a preliminary matter, the existence of other zoonotic diseases does not, and cannot, mean that we must treat all diseases in the same manner and at the same time. We agree that BSE and several other diseases cited by the comments raise public health concerns, but that fact does not mean that we are compelled to promulgate regulations for other or all zoonotic diseases before we can issue regulations to deal with monkeypox. In addition, it is important to note that monkeypox, as we stated in the preamble to the interim final rule (see 68 FR at 62353), is a zoonotic disease that, until mid-2003, occurred in central and west Africa. The monkeypox virus' appearance in the United States demanded our immediate attention because monkeypox is a potentially fatal disease in humans, so it was important to prevent the virus from becoming established in the United States. West Nile virus is an example of how a virus can become established in the United States and result in sickness and death. Before 1999, West Nile virus had not been recorded in the United States; in 2002 alone, more than 4,000 Americans had become ill, and 284 had died (see 68 FR at 62361). Many animal species also suffered as the West Nile virus became established in the United States (id.).

To put it another way, unlike most of the pathogens or factors responsible for the diseases cited by the comments, the monkeypox virus was new to the United States in 2003, and (unlike West Nile virus) could be controlled through regulation of human activity; as a result, a regulatory approach was taken that we anticipated would prevent the virus from becoming established in the listed animal populations or in other domestic animal populations. To the best of our knowledge, the efforts undertaken in 2003 were fully successful.

We also wish to point out that, contrary to the comments' assumptions, we have taken regulatory action regarding other animals and other diseases. Those regulatory actions varied depending on the risk presented. For example, we have issued regulations restricting the sale and commercial distribution of turtles (21 CFR 1240.62) and restricting the transportation of psittacine birds (21 CFR 1240.65) because of their potential to transmit certain diseases to humans. We prohibited the use of mammalian protein in ruminant feed (21 CFR 589.2000) and have taken a number of additional actions to reduce the potential risk of BSE in cattle (see, e.g., 72 FR 1582 (January 12, 2007) (proposed rule to prohibit the use of certain cattle material in or in the manufacture of drugs intended for use in ruminant animals); 70 FR 58570 (October 6, 2005) (proposed rule to prohibit the use of certain cattle origin materials in the food or feed of all animals); 69 FR 58448 (September 30, 2004) (notice of availability of a guidance titled ''Use of Material from Bovine Spongiform Encephalopathy-Positive Cattle in Animal Feed''); 69 FR 42288 (July 14, 2004) (advance notice of proposed rulemaking inviting comment on Federal measures to mitigate BSE risks)). We also have taken action to prohibit the use of certain cattle material (such as brain, skull, eyes, spinal cord, and other material) in human food to minimize human exposure to materials that are highly likely to contain the BSE agent (see 69 FR 42256 (July 14, 2004); see also 69 FR 42275 (July 14, 2004) (proposed rule to require manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain material from cattle to establish and maintain records sufficient to demonstrate that the food or cosmetic is not manufactured from, processed with, or does not otherwise contain prohibited cattle materials)). Thus, we have taken regulatory actions when necessary to protect the public health, and the nature of the risk presented shaped our regulatory response to that risk.

Finally, insofar as rabbits and monkeypox are concerned, we acknowledge that a report issued as the 2003 outbreak was unfolding (Ref. 24) suggested that a rabbit might have transmitted the monkeypox virus to a human. However, subsequent tests on the rabbit in question and the human patient proved negative. Consequently, there are no documented cases of monkeypox transmission from rabbits to humans in the United States (Ref. 22).

• The 2003 monkeypox outbreak was significant because it involved a potentially fatal disease that had never been seen within the United States. It was important to stop monkeypox from becoming established in the United States because, once established, the disease could become a greater public health problem. If the virus became established in the United States, the potential impact on humans and other animal species could have been significant. In brief, final analysis of the 2003 monkeypox outbreak showed the following: (1) Besides rope squirrels, additional native species of African rodents (Gambian giant pouched rats and dormice) are susceptible to monkeypox; (2) prairie dogs are susceptible to monkeypox; (3) infected prairie dogs can transmit the disease to humans; and (4) children may be affected more severely than adults. Additionally, laboratory experiments demonstrated that additional North American animal species are susceptible to monkeypox (Ref. 23). We did not know, in 2003, and, in many cases, still do not know, whether the virus had spread or could spread to other domestic animal species (such as rodents) which, in turn, could expose more humans to monkeypox. In short, when dealing with a novel communicable disease, trying to prevent the disease from spreading has both present effects (i.e., fewer individuals become sick or die) and future effects (i.e., the potential for more animals and humans to become infected decreases if prevention efforts are successful).

• With respect to the comments that supported the interim final rule, we agree that the risks of communicable disease spread justified the measures taken in the interim final rule. Because we have decided to remove the regulation, we will not address the details of the comments that suggested variations on the permit system or other modifications to the rule. Nor will we address the issues related to other diseases of prairie dogs or to zoonotic diseases in general, which are outside the scope of this rule.

• The circumstances being addressed by most of the comments supporting the interim final rule have changed significantly, in large part because of the success of the interim final rule. As

discussed in section III.C above, the current evidence supports the conclusion that the risk of further infections from the monkeypox virus in the United States is low. Only one comment challenged the risk assessment that concluded that the current risk is low, but that comment did not challenge the authors' methodology. Instead, the comment expressed concern about future illegal importation of African rodents or legal importation of other animals that could be infected with monkeypox. Although we agree that the risk of future importations of animals infected with the monkeypox virus is not zero, we believe that the restrictions in 42 CFR 71.56 have been successful, and will continue to be successful, in keeping this risk low. Together, the measures taken by FDA and CDC under 21 CFR 1240.63 and 42 CFR 71.56 have successfully brought the risk of further human or animal monkeypox infection in the United States associated with the 2003 outbreak to its current low level. Based on the evidence, we believe that the risk will remain low in the absence of the measures in FDA's interim final rule. Under these circumstances, including the fact that CDC's interim final rule at 42 CFR 71.56 remains in effect, we have decided to remove 21 CFR 1240.63 in its entirety.

V. Environmental Impact Analysis

We have determined under 21 CFR 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

We have examined the impacts of this regulatory action 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). We believe that the removal of the regulation is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the removal of FDA's regulation would eliminate most of the small administrative costs imposed by the interim final rule, we certify that it 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 publishing ''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 $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. We do not expect the removal of FDA's regulation to result in any 1-year expenditure that would meet or exceed this amount.

We issued a regulation on November 4, 2003, that modified existing restrictions on the import, capture, transport, sale, barter, exchange, distribution and release of African rodents, prairie dogs and certain other animals in order to prevent the spread of monkeypox. The decision to remove the regulation pertaining to domestic trade in prairie dogs and certain African rodents will eliminate most of the costs of the regulation to the extent that they have been realized.

In the interim final rule, we stated that incomplete data precluded us from developing quantitative estimates of the economic costs and benefits of the rule. The analysis of the rule, however, did contain a discussion about the sale of prairie dogs prior to and immediately after the June 11, 2003, administrative order banning the sale of these animals in order to reduce the spread of monkeypox. In effect, the analysis described the loss of the market for these pets that resulted from the earlier administrative order restricting their further distribution. The removal of the regulation would reopen the domestic market for pet prairie dogs, which prior to 2003 was estimated at about 30,000 animals per year with a retail value of about $4.5 million. The domestic markets for certain African rodents would also be reopened, but the CDC restrictions on the importation of African rodents would remain in effect. Although we do not have data to estimate the size of these markets in 2003, the analysis in the interim final rule concluded that they would be fairly small.

The interim final rule also allowed for exemptions from the rule's restrictions on trade in these animals by requesting written permission from FDA. The analysis estimated that individuals requesting these exemptions would incur annual administrative costs ranging from about $3,500 to $6,500. FDA's administrative costs to process these requests each year were estimated at $13,300. These administrative costs will be eliminated with the removal of FDA's regulation.

The analysis of the interim final rule also concluded that the regulation may have a significant impact on a substantial number of small entities, including trappers and distributors of prairie dogs, other small animal distributors, and retail pet stores. Most of these impacts will be negated with the removal of FDA's regulation.

VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Khodakevich, L., Jezek, Z. and Messinger, D., ''Monkeypox Virus: Ecology and Public Health Significance,'' *Bulletin of the World Health Organization*, 66: 747–752 (1988). This reference identifies several species of squirrels as playing a major role as a reservoir for the monkeypox virus.

2. Centers for Disease Control and Prevention, ''Updated Interim Case Definition for Human Case of Monkeypox,'' dated July 2, 2003.

3. Centers for Disease Control and Prevention, ''Questions and Answers About Monkeypox,'' dated July 7, 2003.

4. Centers for Disease Control and Prevention, ''Update: Multistate Outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003,'' *Morbidity and Mortality Weekly Report*, 52: 642–646 (July 11, 2003).

5. Reed, K. D. et al., ''The Detection of Monkeypox in Humans in the Western Hemisphere,'' *New England Journal of Medicine*, 350: 342–350 (January 22, 2004).

6. DiGiulio, D. B., and Eckburg, P. B., ''Human Monkeypox: An Emerging Zoonosis,'' *The Lancet—Infectious Diseases* 4: 15–25 (2004).

7. Centers for Disease Control and Prevention, ''Update: Multistate Outbreak of Monkeypox - Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003,'' *Morbidity and Mortality Weekly Report*, 52: 561–564 (June 20, 2003).

8. Reynolds, G., ''Why Were Doctors Afraid to Treat Rebecca McLester?'' *New York Times Magazine*, section 6, page 32, column 1 (April 18, 2004) (available at *www.nytimes.com/2004/04/18/magazine/18MONKEYPOX.html*).

9. Huhn, G.D., et al., ''Clinical Characteristics of Human Monkeypox, and Risk Factors for Severe Disease,'' *Clinical Infectious Diseases* 41: 1742–1751 (2005).

10. Order dated June 11, 2003, signed by Julie Louise Gerberding, Director, Centers for Disease Control and Prevention, and Mark B. McClellan, Commissioner of Food and Drugs, titled ''Joint Order of the Centers for Disease Control and Prevention and the Food and Drug Administration, Department of Health and Human Services.''

11. 68 FR 36566 (June 18, 2003).

12. Fleischauer, A. T., et al., ''Evaluation of Human-to-Human Transmission of Monkeypox from Infected Patients to Health Care Workers,'' *Clinical Infectious Diseases*, 40: 689–694 (2004).

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14. Likos, A.M., et al., ''A Tale of Two Clades: Monkeypox Viruses,'' *Journal of General Virology* 86: 2661–2672 (2005).

15. Nalca, A., Rimoin, A.W., Bavari, S. and Whitehouse, C.A., ''Reemergence of Monkeypox: Prevalence, Diagnostics, and Countermeasures,'' *Clinical Infectious Diseases* 41: 1765–1771 (2005).

16. Kile, J.C., et al., ''Transmission of Monkeypox Among Persons Exposed to Infected Prairie Dogs in Indiana in 2003,'' *Archives of Pediatric Adolescent Medicine* 159: 1022–1025 (2005).

17. Guarner, J. et al., ''Monkeypox Transmission and Pathogenesis in Prairie Dogs,'' *Emerging Infectious Diseases*, 10: 426–431 (March 2004).

18. Bernard, S., and Anderson, S., ''Qualitative Risk Assessment: Monkeypox in the United States Associated with Domestic Trade in Certain Animal Species,'' *Emerging Infectious Diseases*, 12: 1827–1833 (2006).

19. Anderson, M.G., et al., ''A Case of Severe Monkeypox Virus Disease in an American Child: Emerging Infections and Changing Professional Values,'' *Pediatric Infectious Disease*, 22: 1093–1096 (2003).

20. Croft, D.R., et al., ''Occupational Risks during a Monkeypox Outbreak, Wisconsin, 2003,'' *Emerging Infectious Diseases*, 13: 1150–1157 (2007).

21. Reynolds, M.G., et al., ''Spectrum of Infection and Risk Factors for Human Monkeypox, United States, 2003,'' *Emerging Infectious Diseases*, 13: 1332–1339 (2007).

22. Reed, K. D., Davis, J. P., and Damon, I. K., ''Monkeypox in the Western Hemisphere,'' (Response to a Letter to the Editor), *New England Journal of Medicine*, 350: 1791 (April 22, 2004).

23. Hutson, C.L., et al., ''Monkeypox Zoonotic Associations: Insights from Laboratory Evaluation of Animals Associated with the Multi-State US Outbreak,'' *American Journal of Tropical Medicine and Hygiene*, 76: 757–767 (2007).

24. Centers for Disease Control and Prevention, ''Multistate Outbreak of Monkeypox - Illinois, Indiana, and Wisconsin, 2003,'' *Morbidity and Mortality Weekly Report*, 52: 537–540 (June 13, 2003).

VIII. Federalism

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

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

■ Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR 16 and 1240 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.1 [Amended]

■ 2. Section 16.1 is amended in paragraph (b)(2) by removing the entry for ''§ 1240.63(c)(3) ''.

PART 1240—CONTROL OF COMMUNICABLE DISEASES

■ 3. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1240.63 [Removed]

■ 4. Remove § 1240.63.

Dated: August 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20779 Filed 9–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. FDA–2007–N–0379] (formerly Docket No. 2007N–0280)

Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its regulations on current good manufacturing practice (CGMP) requirements for finished pharmaceuticals as the culmination of the first phase of an incremental approach to modifying the CGMP regulations for these products. This rule revises CGMP requirements primarily concerning aseptic processing, verification of performance of operations by a second individual, and the use of asbestos filters. We are amending the regulations to modernize or clarify some of the requirements as well as to harmonize them with other FDA regulations and international CGMP standards.

DATES: This rule is effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Mary Malarkey, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8268; or

Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., rm. 4364, Silver Spring, MD 20993, 301–796–3279.

SUPPLEMENTARY INFORMATION:

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I. Background

Since the development of the CGMP regulations for drug products in 1962, FDA has balanced the need for easily understood minimum standards with the need to encourage innovation and the development of improved manufacturing technologies. We strive to give manufacturers latitude to determine how to achieve the level of control necessary for CGMP compliance, recognizing that, in some instances, more direction from FDA is necessary to provide a uniform standard to the entire industry, minimize the potential for harm, or achieve some other CGMP objective. We periodically reassess and revise the CGMP regulations to accommodate advances in technology and other scientific knowledge that further safeguard the drug manufacturing process and the public health.

In 1996, as part of this reassessment process, we proposed to: (1) Amend certain requirements of the CGMP regulations for finished pharmaceuticals to clarify certain manufacturing, quality control, and documentation requirements and (2) ensure that the regulations more accurately encompassed current industry practice (61 FR 20104, May 3, 1996) (1996 proposed rule). Subsequently, as a part of the risk-based Pharmaceutical CGMPs for the 21st Century initiative, we created a CGMP Harmonization Analysis Working Group (CGMP Working Group) to analyze related CGMP requirements in effect in the United States and internationally, including those related to quality systems. The CGMP Working Group compared parts 210 and 211 (21 CFR parts 210 and 211) with the CGMPs of the European Union (EU), as well as other FDA regulations (e.g., the Quality Systems Regulation, 21 CFR part 820) to identify the differences and consider the value of supplementing or changing the current regulations. Based on the CGMP Working Group's analysis, we decided to take an incremental approach to modifying parts 210 and 211.

Because of this change in approach, we decided not to finalize the 1996 proposed rule. On December 4, 2007, we published a document withdrawing the 1996 proposed rule (72 FR 68111) (the December 2007 proposed rule). On the same date, we published a direct final rule (72 FR 68064) and companion proposed rule (72 FR 68113) to clarify and modernize certain provisions of the CGMP regulations. The comment period for the direct final rule closed on February 19, 2008. On April 4, 2008, we published a document withdrawing the direct final rule because we received significant adverse comments (73 FR 18440). In the document withdrawing the direct final rule, we explained that the comments received would be considered under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published as a companion to the direct final rule.

After careful consideration of all comments received, we are now publishing this final rule. The final rule represents the culmination of the first increment of modifications to parts 210 and 211.

II. Summary of the Final Rule

The final rule revises the drug CGMP regulations primarily in three areas: Aseptic processing, use of asbestos filters, and verification of operations by a second individual.

A. Aseptic Processing

The final rule revises § 211.113(b) to clarify that required written procedures designed to prevent microbiological contamination of sterile drug products must include procedures on the validation of all aseptic processes in addition to sterilization processes. Other changes related to aseptic processing include the following:

- Revised § 211.67(a) requires that equipment and utensils be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized ''and/or sterilized'' at appropriate intervals to prevent malfunction or contamination. This change recognizes that for sterile drug products, sterilization (sometimes in addition to sanitization) is appropriate.
- Revised § 211.84(d)(6) requires microbiological tests before use of each lot of a component, drug product container, or closure ''with potential for microbiological contamination'' that is objectionable in view of its intended use, consistent with longstanding agency interpretation of this regulation.
- Revised § 211.94(c) requires validation of depyrogenation processes for drug product containers and closures, consistent with longstanding industry practice and agency interpretation of this regulation.
- Revised § 211.110(a) adds bioburden testing to the list (which is not all-inclusive) of in-process control procedures relating to the sampling and testing of in-process materials, which again is consistent with industry practice.

B. Asbestos Filters

We revised §§ 210.3(b)(6) and 211.72 to eliminate provisions permitting limited use of asbestos-containing filters used in processing injectable drug products. We had proposed to simply delete references to asbestos filters in these provisions. However, in response to comments, we also added to § 211.72 the statement ''The use of an asbestos-containing filter is prohibited.'' Also in response to comments, we revised § 211.72 to reflect appropriate technical standards for nonfiber-releasing filters.

C. Verification by a Second Individual

The final rule makes several changes to the regulations to acknowledge, consistent with our longstanding interpretation, that certain operations may be performed by automated equipment and verified by a person, rather than one person performing an operation and another person verifying that the operation was correctly performed. In particular, we added new paragraph (c) to § 211.68 stating that automated equipment used to perform operations addressed in §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements in those sections for the performance of an operation by one person and checking by another person if the equipment is used in conformity with § 211.68 and one person checks that the operations are properly performed. In response to comments, we revised the paragraph to minimize the possibility that the provision might be misinterpreted as requiring a person to repeat by hand all calculations performed by automated equipment.

In accordance with the addition of § 211.68(c), we are adopting corresponding changes to the following provisions:

- Section 211.101(c) and (d) (concerning charge-in of components and containers),
- Section 211.103 (calculation of yields),
- Section 211.182 (equipment cleaning and maintenance), and
- Section 211.188(b)(11) (batch production and control records).

D. Other Minor Changes

In addition to the revisions to the regulations previously noted, we have made minor revisions to the following provisions to provide greater clarity without changing meaning or intent:

- Section 211.82(b) (storage of components, containers, and closures),

- Section 211.84(c)(1) and (d)(3) (collection and testing of samples of components, containers, and closures), and
- Section 211.160(b)(1) (laboratory controls for determining conformity to specifications).

III. Comments on the Proposed Rule and FDA's Response

We received comments on the proposed rule from drug and biologic manufacturers, industry associations, consultants, and other interested persons. A summary of the comments received and our responses follow. We first respond to comments of a general nature and then to comments on the five topics set forth in the preamble of the direct final rule.

To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. Similar comments are grouped together under the same number if the same response would be given for each. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received.

A. General Comments

(Comment 1) One comment stated that it will be very important for FDA to ensure clarity and consistency in the understanding of the final rule among agency staff, including both product reviewers and CGMP inspectors, to minimize different interpretations and applications of these regulations.

(Response) We agree that it is important that FDA employees who perform application reviews, as well as conduct CGMP inspections and other compliance activities, understand these regulations and apply them in a consistent manner in the performance of their duties. Therefore, we will take appropriate steps to ensure that agency staff receive adequate training regarding the new regulations.

(Comment 2) One comment stated that we should not withdraw the 1996 proposed rule because it contained many good features with respect to test method validation and the out-of-specification test result problem. The comment maintained that the guidance for industry entitled ''Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production'' (71 FR 60158, October 12, 2006) is not helpful to people working with biological drugs and other products. Another comment stated that the December 2007 proposed rule should have incorporated many of the changes in the 1996 proposed rule regarding such matters as validation, quality control unit responsibilities, batch failure investigations, and stability samples because they involve some of the most common CGMP deficiencies.

(Response) As we stated in the December 4, 2007, document, we withdrew the 1996 proposed rule because we concluded that, given our new approach to CGMP under the 21st century initiative, it would be preferable to revise the CGMP regulations incrementally rather than in a one-time, comprehensive fashion. Furthermore, we believe that it is appropriate to reevaluate some of the matters considered in the 1996 proposed rule in light of recent scientific and technological advances. We appreciate the comments' interest in the specified CGMP issues, and we will consider these issues in future phases of our CGMP modernization efforts.

(Comment 3) One comment encouraged FDA to consider other CGMP regulations that need modernization or clarification, or are no longer necessary due to technological advances, such as aspects of 21 CFR 610.12 concerning the requirements for bulk sterility testing and allowance for sterility retesting for biological products.

(Response) We appreciate the comment's interest in modernizing CGMP regulations. As previously stated, this final rule represents only our first step in updating the drug CGMP regulations to reflect current industry practice and harmonize the regulations with international CGMP requirements. We will consider other aspects of CGMP in future rulemaking proceedings.

B. Plumbing

Section 211.48(a) requires that potable water be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. It further requires that potable water meet the standards established by the U.S. Environmental Protection Agency (EPA) for primary drinking water in 40 CFR part 141. Proposed § 211.48(a) would have deleted the requirement that the potable water used in a plumbing system meet EPA's standards for primary drinking water, and instead required that the water be ''safe for human consumption.'' This proposed revision was intended to improve harmonization with foreign regulations (particularly those of the EU and Japan) and to make the U.S. regulation more consistent with the United States Pharmacopeia standard. In the preamble of the direct final rule, we stated that the revised requirement could be met by compliance with the standards in the EPA regulations or in the current regulations of the EU or Japan for potable water used to prepare water for pharmaceutical purposes.

(Comment 4) Four comments objected to the proposed change. Among other things, the comments stated that the standard of ''safe for human consumption'' is not sufficiently prescriptive.

(Response) Because of the comments received and other considerations, we have decided not to revise § 211.48(a) at this time. We will address the issue of standards for water used in a facility's plumbing system when we consider proposing regulations for water used as a drug product component in the next phase of our CGMP initiative.

C. Aseptic Processing

In the proposed rule, we sought to amend several regulations on aseptic processing to reflect current industry standards and practices. Some of the proposed revisions would also affect other types of processes and operations. We noted that the proposed changes would not affect the applicability of the guidance for industry entitled ''Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice'' (Aseptic Processing Guidance), issued on October 4, 2004 (69 FR 59258).

1. Equipment Cleaning and Maintenance (§ 211.67(a))

The version of § 211.67(a) amended by this final rule stated: ''Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.'' We proposed to add the phrase ''and/or sterilized'' after the word ''sanitized'' in § 211.67(a) to reflect the fact that sterilization is appropriate for sterile drug products.

On our own initiative, we have revised § 211.67(a) to state that equipment and utensils shall be cleaned, maintained, ''and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals * * *.'' This revision does not alter the meaning of the proposed rule change, but clarifies that for some equipment and utensils

used in the production of certain drug products, sanitization is appropriate; for other equipment and utensils, sterilization is appropriate; and for still others, both sanitization and sterilization are appropriate.

(Comment 5) One comment stated that it is not appropriate to address sterilization in § 211.67(a). Instead, the comment recommended that a reference to sterilization of equipment and utensils be added to § 211.113(b), which requires the adoption of written procedures designed to prevent microbiological contamination of drug products purporting to be sterile.

(Response) We do not agree with the comment because, as previously noted, equipment and utensils used in the production of sterile drug products must be sterilized, not merely sanitized. In addition, we have revised § 211.113(b) as discussed in section III.C.5 of this final rule.

(Comment 6) One comment suggested that we could simplify the language in this regulation by changing the phrase ''beyond the official or other established requirements'' to ''beyond the established (or other official) requirements.''

(Response) We do not believe that the suggested change simplifies the current phrase, which we believe is clear. Therefore, we do not believe that the suggested change is necessary.

(Comment 7) One comment stated that § 211.67(a) should not apply to the production of medical gases because most medical gas manufacturing lines are product-specific, closed systems that are not subject to cleaning or sanitation as part of an established periodic cycle, but instead are specially cleaned to be ''oxygen ready'' and carefully handled in accordance with established procedures. The comment maintained that additional cleaning efforts beyond the initial cleaning regimen substantially increase the risk of introducing contaminants into the system. Therefore, the comment stated, it is not necessary to require cleaning of equipment at ''appropriate intervals'' for medical gas manufacturing. The comment suggested that, alternatively, it might be appropriate for the agency to state that medical gases may represent unique circumstances that will be reflected in a separate guidance.

(Response) We decline to exempt medical gases from the requirements of § 211.67(a) as recommended because this would exceed the scope of our proposed change to clarify that sterilization is appropriate for sterile drug products and would instead focus on whether there is any need for periodic cleaning of medical gas systems. We might consider in a future CGMP rulemaking whether it is appropriate to revise § 211.67(a) to address its application to medical gases.

2. Microbiological Testing of Objectionable Lots of Components, Drug Product Containers, and Closures (§ 211.84(d)(6))

The version of § 211.84(d)(6) amended by this final rule stated: ''Each lot of a component, drug product container, or closure that is liable to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.'' We proposed to change the phrase ''that is liable to microbiological contamination'' to ''with potential for microbiological contamination.''

(Comment 8) One comment stated that the proposed change was unnecessarily restrictive and might lead to testing every lot when the risk of microbial contamination is low and the impact on the intended use is insignificant. This comment suggested replacing ''that is liable to microbial contamination'' with ''prone to microbial contamination.'' One comment stated that the proposed change could make it more difficult for drug manufacturers to replace a less effective, quality control-based inspection and test method with a more modern and effective quality audit method. The comment stated that because the bioburden of dry items such as vials and stoppers is often heterogeneous, improved assurance of this quality attribute is better achieved through the audit, selection, and control by the manufacturers of these items. This comment maintained that knowledge of and control over the manufacturing processes for containers and closures might fall short of justifying that those products do not have a ''potential for contamination.''

(Response) We decline to adopt the recommended change to § 211.84(d)(6) from ''that is liable to microbial contamination'' to ''prone to microbiological contamination.'' We believe that our proposed change to ''with potential for microbiological contamination'' clarifies our longstanding interpretation of the regulation that each lot of component, drug product container, or closure that is susceptible to contamination must undergo microbiological testing before use. Therefore, we have revised § 211.84(d)(6) to refer to components, containers, or closures ''with potential for microbiological contamination'' as proposed.

3. Validation of Depyrogenation of Drug Product Containers and Closures (§ 211.94(c))

The version of § 211.94(c) amended by this final rule stated: ''Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.'' In the preamble to the direct final rule, we stated that it has been longstanding industry practice to validate the sterilization and depyrogenation processes used for drug product containers and closures to ensure consistent removal of microbial contamination and pyrogens or endotoxins. Therefore, we proposed to add a provision to § 211.94(c) requiring the validation of these depyrogenation processes.

(Comment 9) One comment suggested that we require validation of ''sterilization'' as well as depyrogenation processes.

(Response) We do not believe that the suggested change is needed because § 211.113(b) already requires validation of sterilization processes for the prevention of microbiological contamination of drug products purporting to be sterile.

(Comment 10) Four comments objected to the requirement in existing § 211.94(c) because it requires depyrogenation of components based on the nature of the drug and does not take into account the fact that some containers and closures are inherently nonpyrogenic, have been qualified not to require active depyrogenation, or do not require depyrogenation because of handling procedures. Three of the comments proposed that in addition to the nature of the drug, the drug's manufacturing process be included as a factor in determining when containers and closures must be sterilized and processed to remove pyrogenic properties. Two of the comments recommended that the requirement to validate depyrogenation processes be limited to containers and closures that are made nonpyrogenic by a designated depyrogenation process (thus excluding inherently nonpyrogenic containers and closures from the regulation).

(Response) We decline to adopt the suggested revisions because they go beyond the scope of our proposed change to require validation of depyrogenation processes and instead focus on the need for depyrogenation itself.

4. Inclusion of Bioburden Testing in In-Process Testing (§ 211.110(a))

Section 211.110(a) requires that written procedures be established and followed that describe in-process controls and tests or examinations to be conducted on samples of in-process materials of each batch of a drug product. The regulation specifies five control procedures that must be established, where appropriate, to monitor the output and to validate the performance of manufacturing processes that may be responsible for causing variation in the characteristics of in-process material and the drug product. We proposed to add bioburden testing to this list (which is not all-inclusive) because testing for bioburden is standard industry practice for in-process materials and drug products that are produced by aseptic processing.

(Comment 11) Three comments objected to the addition of bioburden testing to § 211.110(a). One comment objected to the inclusion of any specific test and suggested that specific tests be addressed in agency guidance. One comment stated that bioburden testing is not conducted at the same time as other tests specified in § 211.110(a) and is not an in-process test or control because it does not yield immediate results that allow for process adjustment. The comment stated that it would be more appropriate to address bioburden testing in § 211.84. One comment suggested that because § 211.110 covers the sampling and testing of all in-process materials and drug products, adding bioburden testing as a mandatory control procedure could expand current industry validation procedure and produce diversity among the industry and regulators on the circumstances in which validation of bioburden testing is appropriate.

(Response) We do not agree with the comments. As stated in the direct final rule, testing for bioburden is an important in-process control, particularly for drug products that are produced through aseptic processing. Section 211.110(a) provides flexibility to manufacturers so that they need only conduct bioburden testing where the testing is appropriate to assure batch uniformity and drug product integrity. We believe that manufacturers understand for which types of drug products, and at what point in the manufacturing process for these drugs, bioburden testing is appropriate. Accordingly, we have added bioburden testing to § 211.110(a).

5. Control of Microbiological Contamination (§ 211.113(b))

Section 211.113(b) states that appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, must be established and followed. The version of § 211.113(b) amended by this final rule further stated: ''Such procedures shall include validation of any sterilization process.'' We proposed to substitute ''all aseptic and sterilization processes'' for ''any sterilization process.'' As noted in the preamble of the direct final rule, even before we issued the now-replaced guidance on ''Sterile Drug Products Produced by Aseptic Processing'' in 1987, industry routinely conducted validation studies (often referred to as media fills) that substituted microbiological media for the actual product to demonstrate that its aseptic processes were validated (72 FR 68064 at 68066). The proposed change was intended to clarify existing practice and to harmonize § 211.113 with Annex 1 of the EU CGMPs.

(Comment 12) Several comments objected to the proposed change to § 211.113(b) on the basis that aseptic processing cannot be validated. One comment stated that validation of aseptic processing technically cannot be done, although the manufacturer can ensure tight control over the process. One comment stated that aseptic processing simulations demonstrate the capability of a facility, equipment, and operational controls to provide a minimal microbial contamination rate in a single event, but they cannot predict the outcome of a similar process performed at a different time. The comment maintained that to consider aseptic processing to be validated overstates the ability to measure and control the process and could be interpreted as approval to relax the controls necessary for its success. The comment recommended that § 211.113(b) be revised to require validation of ''all sterilization/depyrogenation processes'' and to direct that aseptic processes ''be subjected to periodic assessment to demonstrate the capability of the control strategy to adequately support end product sterility.''

One comment stated that there is currently no means to comply with the proposed requirement to validate aseptic processes. The comment maintained that the microbiological and decontamination methods used in aseptic processing lack the sensitivity, recoverability, and accuracy of the physical and chemical measurement systems normally associated with process validation. The comment further claimed that media fills do not validate aseptic processing because they measure only detectable micro-organisms and do not verify that no micro-organisms exist. The comment stated that although aseptic processing cannot be validated, a state of control can be established, ensuring that the aseptically produced drug consistently meets its specifications and quality attributes. The comment recommended that rather than validation of aseptic processes, § 211.113(b) require ''a formalized quality risk management and control strategy for aseptic processes to provide assurance of requisite and continued process capability and product quality.''

One comment stated that although media fills can evaluate an aseptic process, they cannot be considered to validate the process. The comment recommended that we either not adopt the proposed requirement to validate aseptic processes or provide more clarity on what is expected for validation of aseptic processes. Similarly, another comment recommended that we not revise § 211.113(b) as proposed unless we clarify that more than media fills are required to validate an aseptic process. The comment stated that a well-controlled, robust process is required for aseptic processes and that once a state of control has been established for the process, media fills can be useful in confirming the state of control.

(Response) Although we acknowledge that aseptic process validation does not provide absolute assurance of product sterility, we do not agree that aseptic processes cannot be validated. Validation of aseptic processes, which is a common practice throughout the pharmaceutical industry, means establishing documented evidence that provides a high degree of assurance that a particular process will consistently produce a product meeting its predetermined specifications and quality attributes. Media fills, together with operational controls, environmental controls, and product sterility testing, provide a sufficient level of assurance that drugs purported to be sterile are in fact sterile.

(Comment 13) One comment suggested adding a definition of aseptic processing to part 210.

(Response) We do not believe that it is necessary to define aseptic processing in the regulation. The Aseptic Processing Guidance makes it clear to manufacturers what aseptic processing entails.

(Comment 14) One comment requested confirmation that it is acceptable to follow the current FDA guidance and use media fills to meet the requirement to validate aseptic processes.

(Response) As stated in the preamble to the direct final rule and reiterated previously in this document, manufacturers can follow the recommendations in the Aseptic Processing Guidance to comply with CGMP requirements for aseptic processing, including validation. However, as with any guidance, the Aseptic Processing Guidance is not binding on industry or the agency, and manufacturers may use an alternative approach to achieve compliance if the approach meets the requirements of the act and FDA regulations.

(Comment 15) One comment sought clarification that the requirement to validate aseptic processing would not inhibit implementation of novel technologies recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in the ICH Q8, Q9, and Q10 guidances, or other innovative approaches in these areas.

(Response) We do not believe that the requirement to validate aseptic processing will interfere with the implementation of new technologies either as part of following ICH recommendations or as part of other efforts to meet CGMP requirements. As stated in section I of this document, we have always attempted to balance the need for easily understood minimum CGMP standards with the desire to encourage innovation and the development of improved manufacturing technologies. We are confident that industry can meet the requirement to validate aseptic processing with no adverse impact on technological innovation in drug product manufacturing.

D. Asbestos Filters

As stated in the preamble to the direct final rule, we need to update our regulations on filters used in processing liquid injectable products. The version of § 211.72 amended by this final rule required manufacturers, before using an asbestos-containing filter, to submit proof to FDA that an alternative nonfiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the product. However, we are not aware that asbestos filters are currently commercially manufactured for pharmaceutical use or are used in drug production, and their use is not considered a good manufacturing practice. Therefore, we proposed to delete the reference to the use of asbestos-containing filters from § 211.72 and to delete the reference to asbestos filters from the definition of ''nonfiber-releasing filter'' in § 210.3(b)(6).

(Comment 16) Two comments stated that the regulations should state that the use of asbestos filters is prohibited. One comment stated that if asbestos-containing filters are in fact available and the proposed changes were interpreted as permitting their use, this might pose a risk to patients.

(Response) We agree with the comments. Therefore, in addition to deleting the reference to asbestos-containing filters in § 210.3(b)(6), we have revised the last sentence of § 211.72 to state that the use of an asbestos-containing filter is prohibited.

(Comment 17) One comment recommended that we clarify the second sentence in proposed § 211.72, which stated: ''Fiber-releasing filters may not be used in the manufacture, processing, or packing of these injectable drug products unless it is not possible to manufacture such drug products without the use of such filters.'' The comment recommended that this sentence be revised to state as follows: ''Fiber-releasing filters may be used when/where it is not possible to manufacture such drug products without the use of such filters.''

(Response) We agree with this proposed change and have revised § 211.72 accordingly.

(Comment 18) Four comments recommended revising the following provision in proposed § 211.72: ''If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter of 0.22 micron maximum mean porosity (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product.'' Each of these comments stated that it is technically more accurate to describe a filter in terms of its nominal pore size rating than its mean porosity. One comment stated that the filter pore size standard of 0.22 micron is outdated and should be changed to 0.2 micron.

(Response) These suggested technical changes are consistent with statements in our guidances for industry (e.g., the Aseptic Processing Guidance) concerning filters. Therefore, we have revised § 211.72 to require that if use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron be used.

E. Verification by a Second Individual

The current CGMP regulations include several provisions requiring that certain activities be performed by one person and checked as specified by a second person.

- Section 211.101(c) requires that: (1) Each container of component dispensed for use in manufacturing be examined by a second person to assure that it was released by the quality control unit, (2) the weight or measure is correct as stated in the batch production records, and (3) the containers are properly identified.
- Section 211.101(d) requires that each component be added to the batch by one person and verified by a second person.
- Section 211.103 requires that specified yield calculations be performed by one person and independently verified by a second person.
- Section 211.182 requires the persons performing and double-checking the cleaning and maintenance of major equipment to date and sign or initial equipment logs indicating that the work was performed.
- Section 211.188(b)(11) requires that batch production and control records include identification of the persons performing and directly supervising or checking each significant step in the operation.

When we amended the CGMP regulations in 1978, we established § 211.68, which provides that automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product, subject to the following requirements:

- Equipment is routinely checked according to a program designed to assure proper performance,
- Changes to records are made only by authorized personnel,
- Input and output are checked for accuracy, and
- Appropriate backup of data is maintained.

In the preamble to the 1978 final rule, we stated that the verification requirements in § 211.101 for charge-in of components when automated systems are used would be met if a person verified that the automated system was working properly (43 FR 45014 at 45051, September 29, 1978). Thus, in this situation, the first individual is replaced by a machine or other automated process, and only one person is necessary to verify that the automated system is functioning as intended.

Because we have received questions about the performance and checking requirements in §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) when the operations are performed by automated equipment, such as the widespread and increasing use of computer-controlled operations, we proposed to revise these sections. We proposed to amend these regulations to indicate that when automated equipment is used to perform certain operations, only one person is needed to verify that the automated equipment is functioning adequately. Correspondingly, proposed § 211.68(c) stated that automated equipment used for performance of operations addressed by §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections for the performance of an operation by one person and checking by another person if such equipment is used in conformity with § 211.68 and one person verifies that the operations addressed in those sections are performed accurately by such equipment. We stated in the preamble of the direct final rule that these revisions would clarify our longstanding policy that verification by a second individual may not be necessary when automatic equipment is used under § 211.68.

1. General Comments on Verification

(Comment 19) One comment stated that validated, automated systems equipped with real time alarms that do not require any human intervention should not require human verification. Another comment stated that such systems should not require human verification with each use and, when human verification is needed, the level of verification required should be consistent with the level of automation used. Both of these comments maintained that requiring operator verification of automated, validated equipment under §§ 211.68(c), 211.101(c)(3) and (d), 211.103, and 211.188(b)(11) might hinder the implementation of process analytical technology (PAT) in the drug industry.

(Response) In the **Federal Register** of February 12, 1991 (56 FR 5671) (the 1991 proposal), we issued a proposed rule in part to amend § 211.68 to add what is now the third sentence of § 211.68(b): ''The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system.'' This revision was adopted as part of the final rule issued on January 20, 1995 (60 FR 4087) (the 1995 final rule).

In the 1995 final rule, we responded to several comments on the proposed revision. Two comments suggested that the revised regulation did not accommodate the accepted use of validated computerized drug production and control systems. We declined to change the revision as proposed, stating our belief that the wording in the revised rule adequately encompasses the use of these systems (60 FR 4087 at 4089).

Two comments on the 1991 proposal questioned the need for human verification of operations that are performed by validated computer systems. The comments listed other regulations that were not the subject of the proposed rule that required more than one person to verify certain manufacturing operations, apparently to show that additional personnel would be needed to comply with proposed § 211.68. We noted in the 1995 final rule that the revisions to § 211.68 do not impose any specific personnel requirements. We also noted that the agency is aware that computers are subject to malfunctions, some of which could possibly result in the loss of critical information regarding the manufacturing process or a serious production error and the possible distribution of an adulterated product. Therefore, we stated that while increasingly sophisticated system safeguards and computerized monitoring of essential equipment and programs help protect data, no automated system exists that can completely substitute for human oversight and supervision. We further indicated that while the degree of verification is left to the manufacturer's discretion, the exercise of such discretion under § 211.68 requires the use of routine accuracy checks to provide a high degree of assurance that input to and output from a computer or related system are reliable and accurate. We stated our intent that each manufacturer exercise reasonable judgment based on a variety of factors, including, but not limited to, the complexity of the computer or related system, in developing a method to prevent inaccurate data input and output (60 FR 4087 at 4089).

The December 4, 2007, direct final rule and companion proposed rule were intended to amend the regulations involving second-person checks only to clarify our longstanding policy that verification by a second individual may not be necessary when automatic equipment is used under § 211.68, and that in such situations only one person is needed to verify that the automated equipment is functioning adequately. The amendments were not intended to either add to or detract from any existing requirements in this regard, but only to clarify our longstanding interpretation and policy for these requirements. We note that the same basic considerations apply in this regard today as we expressed in the 1995 final rule. Although increasingly sophisticated controls and safeguards have been implemented for some automated systems, our policy has been that some degree of human oversight, supervision, verification, monitoring, or checking is still necessary to verify proper performance as part of assuring the identity, strength, quality, and purity of drug products. For suitably validated automated systems, even with real time alarms, it is still necessary for a human to verify that the systems are operating as planned and to monitor for abnormalities. We agree that the level, nature, and frequency of such human verification will vary depending on the level of automation used as well as the nature of the system and controls, and the manufacturer has the flexibility and responsibility to determine what is suitable and necessary. Contrary to the comments, we believe that manufacturers can conduct human verification of automated operations in conjunction with the use of PAT in drug production.

For these reasons, we continue to believe that human verification is necessary to ensure that automated systems are functioning properly.

(Comment 20) One comment stated that many current biotech processes include component additions and deletions in a continuous or periodic manner over long periods of time. The comment stated that there would be no added value in requiring a manual verification of this component management scheme in a fully automated scenario.

(Response) For the reasons stated in our response to comment 19, we believe that some degree of human oversight, supervision, verification, monitoring, or checking is a necessary part of CGMP for such processes and that there is added value in having greater assurance that the automated systems are operating properly as intended. We do not expect that each individual component change must be witnessed in person, but rather that a suitable system of human oversight be established and followed to effectively verify that the automated processes are indeed operating correctly in the performance of these operations.

(Comment 21) One comment maintained that our statement in the preamble of the direct final rule that the verifying individual may be, but is not required to be, the operator is a

contradiction of the CGMP regulations, which require (in § 211.25(a)) that all individuals have the education, training, and experience to enable them to perform their assigned functions. The comment asked why the agency would allow an untrained operator to perform a sole verification of a critical step if an automated system is used and recommended that we retract the noted preamble statement.

(Response) The comment incorrectly concluded that allowing the verifying individual to be a person other than the operator would thereby allow an untrained individual to perform the function of verifying a critical step. Section 211.25(a) requires each person performing an assigned function to have the education, training, and experience, or any combination thereof, to enable that person to perform the function. Thus, any person, whether the operator or not, who performs such a verification step would necessarily be required to have the knowledge, training, and experience needed to perform that function. Therefore, our preamble statement does not conflict with the regulations.

(Comment 22) One comment stated that the proposed changes regarding second person verification should be extended to include § 211.188(a), which requires the preparation of batch production and control records that include an accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed. The comment stated that when there is only one signature needed, but the system is automated, it would also follow that no human signature or signature equivalent would be necessary, such as in issuance of a batch record under § 211.188(a), when the record is electronic. The comment also stated that in this case, it is impossible to check the pages for a true and accurate copy. The comment recommended revising § 211.68(c) to include § 211.188(a) in the listing of sections affected and to state that there could be single performance verification under § 211.188(a).

(Response) We do not agree with the recommended changes to § 211.188(a), which would eliminate any human verification of the records. As previously stated, we are clarifying in this rule that the checking of automated equipment by one person can satisfy the requirements of those regulations that address the performance of a step by one person and the verification of the step by a second person. Our proposal regarding verification of operations was intended to make clear that only one person is needed to verify that automated equipment for a processing step is functioning properly; we did not propose deleting all human verification of the step. In addition, we disagree with the comment's apparent contention that no human signature would be needed for issuance of electronic batch production and control records. If such records are generated and issued electronically as part of an automated system, a person must verify that the correct records were issued and that they are still accurate and complete. We believe it is clear that § 211.188(a) requires only one check for accuracy, with date and signature (which could be electronic), and that it does not require a separate second check of this step. Therefore, no changes to § 211.188(a) are necessary or appropriate.

(Comment 23) Three comments addressed second-person verification in § 211.194. Section 211.194(a) requires that laboratory records include complete data derived from all tests necessary to assure compliance with established specifications and standards as specified in that subsection. Section 211.194(a)(7) requires that laboratory records include the initials or signature of the person who performs each test and the date(s) the tests were performed. Section 211.194(a)(8) requires the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards. Two of the comments stated that the principle behind the proposed second-person verification revisions should be extended to § 211.194 to include checking laboratory records involving automated laboratory equipment. The first comment recommended revising § 211.194 generally. The second comment specifically recommended that § 211.194(a)(8) be revised to add that if laboratory tests have been performed by automated equipment under § 211.68, the laboratory record need only include the identification of one person conducting the review of the tests performed by the automated system. The comment also asked that § 211.194(a)(8) be added to the list of sections affected in § 211.68(c). The third comment stated that the failure to include § 211.194(a)(7) and (a)(8) in the proposed revisions implies that the use of automated systems to perform or check testing is not allowed.

(Response) We decline to include § 211.194 among the sections enumerated in § 211.68(c) concerning second-person verification of operations performed by automated equipment. We acknowledge that automated equipment may be used to conduct certain laboratory testing operations. However, when automated equipment is used to perform a laboratory test, typically a person initiates the test and ensures that the correct equipment is used and that it operates properly. In this situation, one person assists in or oversees the performance of the laboratory test and a second person reviews the records for accuracy, completeness, and compliance with established standards. Thus, the use of equipment to perform laboratory tests, though permissible, is not a situation in which automated equipment (rather than a person) performs an operation and a person verifies that performance, which is the situation addressed in revised § 211.68(c). Therefore, it would not be appropriate to include a reference to § 211.194 (or to § 211.194(a)(8) specifically) in revised § 211.68(c).

2. Automatic, Mechanical, and Electronic Equipment (§ 211.68)

(Comment 24) One comment stated that § 211.68 is no longer in line with the technological improvements of the past 30 years and with the increasing knowledge of computer validation by industry and regulators. The comment recommended that § 211.68 be aligned with 21 CFR 820.70(i), section 5.4 of the ICH Q7A guidance entitled ''Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,'' and the Pharmaceutical Inspection Cooperation Scheme's Annex 11 on computerized systems.

(Response) We decline to adopt the suggested revisions because they exceed the scope of our proposed revision of § 211.68, which only addressed second-person verification of operations performed by automated equipment. We might consider revising other provisions of § 211.68 as part of a future rulemaking to update the CGMP regulations and make them consistent with international CGMP provisions.

(Comment 25) One comment recommended that instead of our proposed changes to § 211.68(c) and other regulations concerning second-person verification, we revise § 211.68(a), which permits the use of automatic, mechanical, or electronic equipment in the manufacture, processing, packing, and holding of drug products. The comment stated that the wording of our proposed changes only allows for actions to be performed by automated equipment and checked by a person, which would prevent the introduction of automated systems to check operations performed by a person. The comment also stated that our proposed changes would still require the involvement of at least one person

in each of these circumstances and prevent the use of a controlled system or systems that both perform and independently verify the relevant operations. One comment suggested that rather than our proposed revisions, the desired clarification concerning automated equipment and second-person checks would be better achieved by adding to § 211.68(a) the following sentence: ''Automated equipment can satisfy the requirements for the performance of an operation by one person and/or checking by another person.''

(Response) We do not agree with the recommended change. The proposed rule simply clarified our longstanding position that only one human check is necessary to verify a processing step performed by automated equipment. The suggested revision of § 211.68(a), however, would allow manufacturers to rely solely on automated equipment to verify the human performance of certain processing steps and allow automated equipment to both perform and check operational steps, which would constitute a significant change from the current regulations. As stated in our response to comment 19, we believe that human verification of certain processing steps, even when those steps are performed by automated equipment, is still necessary.

(Comment 26) One comment stated that although proposed § 211.68(c) implies that the automated equipment is doing the work and a person can verify that the work is done, there are cases in which a person does the work and automated equipment might be able to verify the person's work. The comment cited as an example the case in which an automated system scans the bar codes of ingredients and equipment to ensure that the ingredient is correct for use with the equipment for that step in the process, but the physical addition of the ingredient is by the human operator (followed by the automated system scanning). The comment recommended, therefore, that § 211.68(c) be modified to allow both the automated system and the person to do either the performance or the verification tasks for the operations addressed by §§ 211.101(c) or (d), 211.103, 211.182, 211.188(b)(11), or 211.194(a)(8), or a single performance verification in the case of § 211.188(a).

(Response) We acknowledge that it might be possible to design an automated system to verify operations performed by humans, but as stated in our response to comment 19, we continue to believe that some human verification of the processing steps performed by an automated system is necessary.

(Comment 27) One comment suggested revising § 211.68(c) to state that automated equipment can satisfy the requirements for verification of operations addressed by the listed sections as follows: (1) If such unit operation is fully automated, no manual verification is necessary and (2) if there is an operator for the automated equipment, the verifying individual may be, but is not required to be, the operator. The comment gave several reasons for this change:

- Automated, validated systems equipped with real-time alarms that do not require any human intervention should not require human verification because § 211.68(a) adequately addresses the maintenance and verification of performance of these systems.
- The need and type of verification required should be consistent with the level of automation used. For example, operations that are not fully automated and require operator participation may serve as verification of the operator's activities, while fully manual operations would require a second human verification.
- As proposed, § 211.68(c) might hinder the adoption of PAT (e.g., there would be no value added by manual verification when components are charged in a fully automated manner according to a validated algorithm).

(Response) As stated in our response to comment 19, we do not agree with the contention that no human verification is necessary when fully automated systems are used, and we therefore decline to make these requested changes to § 211.68(c). We also do not believe that § 211.68(c) will hinder the adoption of PAT. As stated in the preamble to the direct final rule, we agree that if there is an operator for the automated equipment, the verifying individual may be, but is not required to be, the operator. However, § 211.68(c) does not require that the verifying individual be the operator, and we do not believe that it is necessary that the provision explicitly state that the verifying individual need not be the operator.

(Comment 28) One comment stated that the proposed revision of § 211.68(c), when applied to § 211.188(b), might be more restrictive than FDA's position in Compliance Policy Guide (CPG) Sec. 425.500, Computerized Drug Processing; Identification of ''Persons'' on Batch Production and Control Records (formerly CPG 7132a.08). CPG 425.500 states that when significant steps in the manufacturing, processing, packing, or holding of a batch are performed, supervised, or checked by a computerized system, an acceptable means of complying with the identification requirements in § 211.188(b)(11) would consist of conformance to certain requirements. The comment maintained that CPG 425.500 gives companies the flexibility to automate not only the performance of critical actions but also the supervision and checking of these actions if it is shown that the efficacy of these controls would be at least equivalent to the level of efficacy if the verification were done by a second person. The comment stated that this flexibility should be extended to all CGMP sections in which a verification is requested. The comment therefore asked that § 211.68(c) be revised to state that automated equipment used for performance of operations addressed by §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections for the performance of an operation by one person and checking by another person if such equipment is used in conformity with § 211.68 and one person either performs the operations addressed in those sections under the control of the automated equipment or verifies that these operations are performed accurately by such equipment.

(Response) We do not agree with the comment's apparent interpretation of CPG 425.500 that the CPG allows for elimination of human oversight. The purpose of the CPG is to explain what constitutes ''identification'' of persons in batch records under § 211.188(b)(11) when automated systems are used for various functions. The CPG states that when an automated system is used to perform, directly supervise, or check significant steps in the production of a drug, the identification requirements in § 211.188(b)(11) are met if there is documentation that the system contains adequate checks (and documentation of the performance of the system itself), validation of the system's performance, and recording of specific checks in batch records (including initial, branching, and final steps). These conditions for applying the identification requirements to steps using automated equipment involve the responsibilities of persons. For example, a person, rather than automated equipment, is needed to record these checks of production steps in batch records. Therefore, contrary to the comment's implication, the CPG does not state that human oversight is unnecessary when an automated system is involved in the performance, supervision, or checking of production

steps. All automated systems require some level (commensurate with the complexity and risk inherent in the system) of human oversight or checking for expected performance at appropriate intervals. Therefore, we decline to revise § 211.68(c) as recommended.

(Comment 29) One comment, although supportive of the proposal to allow initial activities to be performed by automated equipment, objected to requiring that the output of an automated and adequately validated activity be checked for accuracy by a person. The comment maintained that the act of having validated software and its related processes itself constitutes an independent check that operations are being performed accurately and argued that this is more reliable than any contemporaneous check by a person. The comment therefore asked that § 211.68(c) be changed to state that independent checks may consist of contemporaneous analysis and verification by a second person following completion of the activity; or, where the automated process has been validated to a high degree of confidence, the prior validation can satisfy this requirement and a second person's check may then consist of verifying the validated status of the equipment and processes.

(Response) We do not agree with the suggested change. Although we agree that it is an important part of process controls to ensure the validated status of equipment and processes even before they are used, we do not believe that verifying this validated status can satisfy the requirement for checking the actual performance of automated equipment. However, we believe that the requirement in proposed § 211.68(c) that one person ''verifies that the operations * * * are performed accurately'' by automated equipment may have led some comments to believe that we were requiring a more specific and detailed repetitive type of check than we intended. When automated equipment is used for operations addressed by revised § 211.68(c) in conformance with § 211.68, the person doing the checking must verify that the automated equipment is functioning properly and that the operations are reliably performed in the intended manner. As discussed in the response to comment 19, the nature and frequency necessary for such verification will vary depending on the level of automation used as well as the nature of the system and controls. We do not expect that it will normally be necessary, under § 211.68(c), for a person to repeat all of the automatic calculations by hand to ensure their accuracy. Therefore, we have revised § 211.68(c) to clarify that automated equipment can be used to perform an operation when the performance is checked by a person provided that ''such equipment is used in conformity with this section [§ 211.68] and one person checks that the equipment properly performed the operation.''

3. Verification of Weighing, Measuring, or Subdividing Operations (§ 211.101(c))

Section 211.101 concerns charge-in of components. Proposed § 211.101(c) stated, in part, that if the weighing, measuring, or subdividing operations for components are performed by automated equipment under § 211.68, only one person is needed to ensure that the requirements in § 211.101(c)(1), (c)(2), and (c)(3) are met.

(Comment 30) One comment proposed broadening § 211.101(c) to clarify that the weighing, measuring, and subdividing operations could be either performed by automated equipment or checked by automated equipment after being performed manually.

(Response) We decline to make this suggested change for the reasons provided in response to comments 19 and 25. Revised § 211.101(c) only permits human checking of weighing, measuring, and subdividing operations performed by automated equipment; we did not propose to allow automated checking of these operations. We continue to believe that human verification of these processing steps is necessary.

(Comment 31) One comment stated that with respect to medical gases, there is no measurement of components to be dispensed for manufacturing that needs to be double-checked to ensure that the right quantity of the right component was added, because transfers of pure gases are within product-specific systems. However, the comment stated, with respect to gas mixtures, it is appropriate to have a verification of hook-ups as different components are added unless there is subsequent purity testing for each component.

(Response) We decline to exempt single gas filling operations from certain requirements of § 211.101(c) as recommended because such a change would exceed the scope of our proposed change to § 211.101(c), which only addressed human checking of weighing, measuring, and subdividing operations performed by automated equipment. We might consider in a future rulemaking whether it is appropriate to exempt medical gases from certain requirements of § 211.101(c).

4. Verification of Components Added to the Batch (§ 211.101(d))

Proposed § 211.101(d) would have required that each component be either added to the batch by one person and verified by a second person or, if the components are added by automated equipment under § 211.68, only verified by one person.

(Comment 32) One comment stated that eliminating a double check for adding materials to a batch is problematic because an error in those operations would be difficult to detect and might not be discovered before the product is distributed, which could result in patient injury and product recall. The comment recommended deleting or modifying the ability to use a sole verifier for operations involving addition of materials.

(Response) The comment appears to suggest that we proposed to eliminate the requirements concerning verification that appropriate components were added to a batch. The revisions we are adopting do not eliminate the requirement to verify performance in § 211.101(d); they simply codify our longstanding policy that components may be added either by a person or by suitable automated equipment. The addition of components still must be checked by a person.

(Comment 33) One comment stated that under the proposed change to § 211.101(d), if a validated system performs a function, it is acceptable for one person to verify that action, but if an automated system prompts an operator to perform a function, a second person would be required to confirm the proper execution of the action. The comment recommended changing § 211.101(d) to state that each component must be added to the batch by one person and verified by a second person, ''unless the components are added by automated equipment under § 211.68, in which case verification can be performed by one person.''

(Response) We decline to accept the suggested change because we do not believe that it constitutes a substantive difference from the language of proposed § 211.101(d). It is irrelevant whether use of a particular automated system for component charge-in requires an operator to perform a related function; in either case, verification of the charge-in operation(s) must be performed by a person.

(Comment 34) One comment recommended changing § 211.101(d) to specify that the weighing, measuring, or subdividing operations might be performed by automated equipment or checked by automated equipment after

being performed manually. The comment also stated that in many instances, the verification by a person of actions performed by automated equipment can only be done on the basis of outputs from the equipment. As an example, the comment stated, when the introduction of components in a liquid production line is fully automated, there is no possibility for the operator to check that the correct amount of materials was incorporated into the batch other than by relying on information given by the same automated equipment. The comment stated that in that case, the verification would consist of confirming that the component's incorporation process was completed without errors or alarms.

(Response) We decline to make this suggested change for the reasons stated in response to comments 19 and 25. Revised § 211.101(d) only permits human checking of component additions performed by automated equipment; we did not propose to allow automated checking of component additions performed by humans. In the example given in the comment, human verification that components were properly added to the liquid production line by the automated equipment would be needed to ensure that the equipment performed properly. We continue to believe that human verification of this processing step is necessary.

5. Calculation of Yield (§ 211.103)

We proposed, in § 211.103, to require that calculations of actual yields and percentages of theoretical yields be performed by one person and independently verified by a second person or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

(Comment 35) One comment stated that it is not necessary to have a person recalculate a yield manually after a validated system does it automatically. The comment asked that § 211.103 be revised to limit the human interaction to data entry and data verification, but not recalculation of yields if yields are calculated by a validated, automated system. A similar comment stated that § 211.103 should be changed to state that if the yield is calculated by automated equipment, a person must verify the data entries, rather than regenerate the calculations.

(Response) We do not believe that the recommended changes are needed or appropriate. Revised § 211.103 does not require that all yield calculations be repeated manually. Manual recalculation might be a suitable approach to verifying yield calculations, but § 211.103 also permits the use of other approaches, including verification that automated equipment functioned properly while performing yield calculations.

(Comment 36) One comment reiterated the views expressed in its comments on the CGMP for medical gases draft guidance. Thus, the comment requested that the requirements for yield calculation in § 211.103 not be applied to medical gases because of the atmospheric-gas-separation and cylinder-filling processes associated with medical gases. In further support of its position, the comment referred to an FDA publication (Human Drug CGMP Notes, vol. 5, no. 2, June 1997) in which the agency stated that it would propose to revise the CGMP regulations to exempt medical gases from the requirements for yield reconciliation.

(Response) We decline to exempt medical gases from the requirements for yield calculation in § 211.103 as recommended because this would exceed the scope of our proposed change to § 211.103, which addressed only human checking of yield calculations performed by automated equipment. We might consider in a future CGMP rulemaking whether it is appropriate to exempt medical gases from certain requirements of § 211.103. In addition, we might consider providing specific recommendations to medical gas manufacturers to help them comply with the requirements for calculating yields in the course of finalizing the draft guidance on CGMP for medical gases.

6. Equipment Cleaning and Use Log (§ 211.182)

We proposed, in § 211.182, to require the persons performing and double-checking equipment cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, only the person verifying the cleaning and maintenance done by the automated equipment) to date and sign or initial the log indicating that the work was performed.

(Comment 37) One comment stated that eliminating a double check for cleaning equipment is problematic because an error in those operations would be difficult to detect and might not be discovered before the product is distributed, which could result in patient injury and product recall. The comment recommended deleting or modifying the ability to use a sole verifier for operations involving equipment cleaning.

(Response) The comment appears to suggest that we proposed to eliminate the requirements concerning verification that equipment was appropriately cleaned and maintained. The revisions we are adopting do not eliminate the requirement to verify performance in § 211.182; they simply codify our longstanding policy that equipment may be cleaned and maintained either by a person or by suitable automated equipment. Cleaning and maintenance of equipment must still be checked by a person.

(Comment 38) One comment stated that operations addressed by §§ 211.182 and 211.188(b)(11) are often performed using semi-automated equipment that requires an operator to select the correct menu. The comment stated that major pieces of equipment such as ''Clean in Place'' (CIP) skids and vial washers often require the operator to select the appropriate process menu before the execution of the actual automated cycle by the equipment's controller. The comment asked whether, when operator input is necessary to select but not perform an operation, the signature of the operator selecting the menu is required in cases when there is a second signature that verifies the performance of the cycle. One comment requested that we verify in § 211.182 or the preamble of the final rule that a single verification remains sufficient when automated but portable cleaning skids are used.

(Response) We do not believe that initiation of the automated cleaning cycle by a human operator constitutes performance of the cleaning process for purposes of revised § 211.182. The revised regulation requires that after an automated cleaning process (such as CIP) is completed, the human operator must date and sign or initial the log verifying that the equipment performed the automated cleaning process properly. The regulation does not require the operator to date and sign or initial the log simply for the initiation of the automated cleaning cycle. This approach applies to both portable equipment skids and fixed equipment.

(Comment 39) One comment stated that in many instances, the human verification of an action performed by automated equipment can only be done on the basis of outputs from the equipment. As an example, the comment stated, when equipment is cleaned through CIP, the verification should consist of confirming that the system reports the cleaning as successfully completed without alarms.

(Response) What constitutes adequate verification that equipment has been properly cleaned or maintained using

automated equipment in accordance with revised § 211.182 depends on the particular circumstances. The outputs from the automated equipment will normally be key factors, but not necessarily the only ones. The manufacturer should determine the reliability of the outputs and periodically check them. For example, it might be appropriate to verify that an alarm is working properly and is successfully monitoring the equipment's critical functions. There might be other ways of verifying the adequate performance of cleaning and maintenance by automated equipment, such as by monitoring the usage of cleaning supplies in a cleaning cycle or conducting an independent check of the rinse.

(Comment 40) One comment stated that for most medical gas systems, routine or periodic cleaning is not performed because the industry is characterized by product-specific closed systems that undergo an appropriate cleaning process before initial use. The comment stated that because of the high number of batches produced on a weekly/monthly basis in the medical gas industry, it is more appropriate to keep cleaning and maintenance records separate from batch records. The comment maintained that although requiring documentation of equipment cleaning, maintenance, and use in individual equipment logs may be appropriate for traditional pharmaceuticals (where key processing equipment may be used for multiple products and lot numbers), applying this requirement to medical gases would make retrieval and management of cleaning and maintenance records much more difficult. The comment added that use logs are not appropriate for medical gases because batch record documentation provides a consecutive listing of products manufactured on each system.

(Response) We decline to exempt medical gases from certain requirements of § 211.182 as recommended because this would exceed the scope of our proposed change to § 211.182, which addressed human verification of cleaning steps performed by automated equipment. We might consider in a future CGMP rulemaking whether it is appropriate to exempt medical gases from certain requirements of § 211.182.

7. Batch Production and Control Records (§ 211.188(b)(11))

Section 211.188 concerns batch production and control records. Proposed 211.188(b)(11) specified that when a significant step in the operation is performed by automated equipment under § 211.68, the record would need to identify the person checking the significant step performed by the automated equipment.

(Comment 41) One comment stated that § 211.188(b)(11) should be changed to state that a significant manufacturing step could be either performed or checked by automated equipment. The comment stated that this approach is permitted by CPG 425.500.

(Response) We decline to make this suggested change. As stated in our response to comment 28, CPG 425.500 does not, as the comment implies, state that human oversight is unnecessary when an automated system is involved in the performance, supervision, or checking of production steps. To revise § 211.188(b)(11) as recommended by the comment might be interpreted as permitting manufacturers to rely solely on automated equipment to verify the human performance of certain production steps. As stated in our response to comments 19 and 25, we believe that human verification of processing steps is still necessary.

F. Miscellaneous Minor Changes Based on 1996 Proposal

We proposed to make miscellaneous minor changes to CGMP regulations to clarify certain manufacturing, quality control, and documentation requirements and to align the regulations with industry practice.

1. Storage of Untested Components, Drug Product Containers, and Closures (§ 211.82(b))

The version of § 211.82(b) amended by this final rule stated: ''Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, as appropriate, and released.'' We proposed to replace the phrase ''as appropriate'' with the phrase ''whichever is appropriate'' to eliminate any ambiguity in § 211.82(b) and to emphasize that it is accepted industry practice to conduct some testing or examination before components, drug product containers, or closures are released from quarantine.

(Comment 42) One comment requested that medical gas container-closure assemblies returned from customers and reused be exempted from § 211.82(b). The comment stated that assembled cylinder/valve medical gas combinations are reused and handled differently than they would be at the time of initial receipt. The comment stated that returned assemblies are individually inspected for all critical quality issues immediately before filling; those assemblies that do not meet the inspection criteria are moved to a quarantine area. The comment stated that this practice satisfies the intention that components, containers, and closures be inspected to ensure that unacceptable assemblies are not used in the manufacturing process.

(Response) Under revised § 211.82(b), manufacturers of medical gases would retain the ability to sequester and inspect returned valve/cylinder assemblies before refilling in accordance with the industry practice described by the comment. The practice described by the comment is to have the assembled valve/cylinders placed in a segregated area (apparently not identified using the word ''quarantine''), examined for conformance to quality standards, and, if the criteria are met, immediately made available for refilling. This practice would meet the requirement for a quarantine status if goods in such areas or under such a status are not acceptable for use as-is unless and until they are qualified to be suitable for use. Therefore, we do not believe that the practice as described violates revised § 211.82(b), and there is no need to exempt medical gas manufacturers from this requirement.

2. Cleaning of Component Container Samples (§ 211.84(c)(1))

The version of § 211.84(c)(1) amended by this final rule stated: ''The containers of components selected [for sampling] shall be cleaned where necessary, by appropriate means.'' We proposed to replace the phrase ''where necessary, by appropriate means'' with the phrase ''when necessary in a manner to prevent introduction of contaminants into the component.'' This change was intended to clarify that the act of cleaning is done for a particular purpose—to prevent the introduction of contaminants—and must be done unless cleaning is not necessary to prevent contamination.

(Comment 43) One comment expressed concern that the proposed change might be interpreted to require validation of this prevention of contamination during sampling. The comment requested that we confirm that our intent is to place the contamination concern into the controls and procedures for sampling and into the training of staff who perform these activities, rather than to require validation of the absence of contamination.

(Response) Revised § 211.84(c)(1) does not require manufacturers to conduct validation studies to prove that the method of sampling prevents contamination. When properly designed and followed, the cleaning procedures, training, and facility and equipment

controls, along with supervisory and quality unit oversight, should ensure compliance with § 211.84(c)(1).

3. Editorial Changes (§§ 211.84(d)(3) and 211.160(b)(1))

We proposed minor editorial changes to two regulations, §§ 211.84(d)(3) and 211.160(b)(1). The version of § 211.84(d)(3) amended by this final rule stated: ''Containers and closures shall be tested for conformance with all appropriate written procedures.'' We proposed to replace the word ''conformance'' with ''conformity'' and the word ''procedures'' with ''specifications.'' The first sentence of the version of § 211.160(b)(1) amended by this final rule stated: ''Determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products.'' We proposed to replace the word ''conformance'' with ''conformity'' and the word ''appropriate'' with ''applicable.'' We stated in the preamble to the direct final rule that these revisions would provide clarity without changing the meaning or intent of these regulations. We received no comments on these proposed changes, and we have revised these provisions as proposed.

IV. Analysis of Impacts

FDA has examined the impacts of this 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, because the rule either clarifies the agency's longstanding interpretation of, or increases latitude for manufacturers in complying with, existing CGMP requirements.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule does not impose any new regulatory obligations, the agency believes that the 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 $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. This rule does not result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to update the codified language to reflect current practice and to harmonize requirements in the CGMP regulations with requirements in other regulations and with international CGMP standards. It does not impose any additional requirements; therefore, industry will not incur incremental compliance costs for these proposed changes.

V. Environmental Impact

FDA concludes that issuing these clarifying amendments to the CGMP regulations will not have a significant impact on the human environment. Therefore, an environmental impact statement is not required.

VI. Federalism

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

VII. Paperwork Reduction Act of 1995

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information (recordkeeping requirements) in part 211 have already been approved by OMB under control number 0910–0139. The final rule amends certain sections of part 211 as well as § 210.3 (§ 210.3 does not contain information collection requirements). As concluded in section IV of this document, ''Analysis of Impacts,'' the purpose of the final rule is to update the regulations to reflect current practice and to harmonize requirements in the CGMP regulations with requirements in other regulations and with international CGMP standards. The final rule does not impose any additional requirements. Thus, because the final rule does not substantively revise the information collection requirements in part 211 or add new information collection requirements, there is no need to conduct an analysis under the PRA.

List of Subjects

21 CFR Part 210

Drugs, Packaging and containers.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 210 and 211 are amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

■ 1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. Section 210.3 is amended by revising paragraph (b)(6) to read as follows:

§ 210.3 Definitions.

(b) * * *

(6) *Nonfiber releasing filter* means any filter, which after appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered.

* * * * *

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 3. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 4. Section 211.67 is amended by revising paragraph (a) to read as follows:

§ 211.67 Equipment cleaning and maintenance.

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

* * * * *

■ 5. Section 211.68 is amended by adding paragraph (c) to read as follows:

§ 211.68 Automatic, mechanical, and electronic equipment.

* * * * *

(c) Such automated equipment used for performance of operations addressed by §§ 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation.

■ 6. Section 211.72 is revised to read as follows:

§ 211.72 Filters.

Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. The use of an asbestos-containing filter is prohibited.

■ 7. Section 211.82 is amended by revising paragraph (b) to read as follows:

§ 211.82 Receipt and storage of untested components, drug product containers, and closures.

* * * * *

(b) Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area shall conform to the requirements of § 211.80.

■ 8. Section 211.84 is amended by revising paragraphs (c)(1), (d)(3), and (d)(6) to read as follows:

§ 211.84 Testing and approval or rejection of components, drug product containers, and closures.

* * * * *

(c) * * *

(1) The containers of components selected shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component.

* * * * *

(d) * * *

(3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.

* * * * *

(6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.

* * * * *

■ 9. Section 211.94 is amended by revising paragraph (c) as follows:

§ 211.94 Drug product containers and closures.

* * * * *

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated.

* * * * *

■ 10. Section 211.101 is amended by revising paragraphs (c) and (d) to read as follows:

§ 211.101 Charge-in of components.

* * * * *

(c) Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that:

(1) The component was released by the quality control unit;

(2) The weight or measure is correct as stated in the batch production records;

(3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under § 211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(d) Each component shall either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment under § 211.68, only verified by one person.

■ 11. Section 211.103 is revised to read as follows:

§ 211.103 Calculation of yield.

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

■ 12. Section 211.110 is amended by revising paragraph (a) introductory text and by adding paragraph (a)(6) to read as follows:

§ 211.110 Sampling and testing of in-process materials and drug products.

(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

* * * * *

(6) Bioburden testing.

* * * * *

■ 13. Section 211.113 is amended by revising paragraph (b) to read as follows:

§ 211.113 Control of microbiological contamination.

* * * * *

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

■ 14. Section 211.160 is amended by revising paragraph (b)(1) to read as follows:

§ 211.160 General requirements.

* * * * *

(b) * * *

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

* * * * *

■ 15. Section 211.182 is revised to read as follows:

§ 211.182 Equipment cleaning and use log.

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

■ 16. Section 211.188 is amended by revising paragraph (b)(11) to read as follows:

§ 211.188 Batch production and control records.

* * * * *

(b) * * *

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

* * * * *

Dated: August 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20709 Filed 9–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 501

Economic Sanctions Enforcement Guidelines

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule with request for comments.

SUMMARY: The Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury is issuing this interim final rule, ''Economic Sanctions Enforcement Guidelines,'' as enforcement guidance for persons subject to the requirements of U.S. sanctions statutes, Executive orders and regulations. This interim final rule supersedes the Economic Sanctions Enforcement Guidelines set forth in OFAC's proposed rule of January 29, 2003 [1] (with the exception of the proposed Appendix to the Cuban Assets Control Regulations, 31 CFR Part 515, set forth therein) and the Economic Sanctions Enforcement Procedures for Banking Institutions set forth in OFAC's interim final rule of January 12, 2006.[2] These Enforcement Guidelines are published as an appendix to the Reporting, Procedures and Penalties Regulations, 31 CFR Part 501.

DATES: The interim final rule is effective September 8, 2008. Written comments may be submitted on or before November 7, 2008.

ADDRESSES: You may submit comments by any of the following methods: *Federal eRulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

Fax: Attn: Request for Comments (Enforcement Guidelines) (202) 622–1657.

Mail: Attn: Request for Comments (Enforcement Guidelines), Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that appears at the end of this document. Comments received will be made available to the public via regulations.gov or upon request, without change and including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Elton Ellison, Assistant Director, Civil Penalties, (202) 622–6140 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*http://www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: (202) 622–0077.

Procedural Requirements

Because this interim final rule imposes no obligations on any person, but only explains OFAC's enforcement policy and procedures based on existing substantive rules, prior notice and public comment are not required pursuant to 5 U.S.C. 553(b)(A). Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. This interim final rule is not a significant regulatory action for purposes of Executive Order 12866.

Although a prior notice of proposed rulemaking is not required, as discussed in more detail below, OFAC is soliciting comments on this interim final rule in order to consider how it might make improvements to these Guidelines. Comments must be submitted in writing. The addresses and deadline for submitting comments appear near the beginning of this notice. OFAC will not accept comments accompanied by a request that all or part of the submission be treated confidentially because of its business proprietary nature or for any other reason. All comments received by the deadline will be a matter of public record and will be made available to the public via regulations.gov.

The collections of information related to the Reporting, Procedures and Penalties Regulations have been previously approved by the Office of Management and Budget (OMB) under control number 1505–0164. A small adjustment to that collection has been submitted to OMB in order to take into account the voluntary self-disclosure process set forth in these Guidelines. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. This collection of

[1] 68 FR 4422–4429 (January 29, 2003).

[2] 71 FR 1971–1976 (January 12, 2006).

information is described in subpart F of Part I, subpart G of part III and subpart B of part V of these Guidelines, which will constitute the new Appendix to part 501. The referenced subparts explain that the voluntary self-disclosure of an apparent violation to OFAC will be considered in determining the appropriate agency response to the apparent violation and, in cases where a civil monetary penalty is deemed appropriate, the base penalty amount and the proposed penalty amount. As set forth in subpart B of part V of the Guidelines, an apparent violation involving a voluntary self-disclosure will result in a base penalty amount at least 50 percent less than the base penalty amount in similar cases that do not involve a voluntary self-disclosure. This provides an incentive for persons who have or may have violated economic sanctions laws to come forward and provide OFAC information that it can use to better enforce its economic sanctions programs. The submitters who will likely seek to avail themselves of the benefits of voluntary self-disclosure are financial institutions, businesses, other entities, and individuals who find that they have or may have violated a sanctions prohibition and wish to disclose their actual or potential violation.

The estimated total annual reporting and/or recordkeeping burden: 1,250 hours. *The estimated annual burden per respondent/record keeper:* 10 hours. *Estimated number of respondents and/or record keepers:* 125. *Estimated annual frequency of responses:* Once or less, given that OFAC expects that persons who voluntarily self disclose their violations will take better care to avoid future violations. *Comments are invited on:* (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Comments concerning the above information, the accuracy of the estimated average annual burden, and suggestions for reducing this burden should be directed to OMB, Paperwork Reduction Project, control number 1505–0164, Washington, DC 20503, with a copy to the Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220. Any such comments should be submitted no later than November 7, 2008. Comments on aspects of this rule other than those involving collections of information subject to the Paperwork Reduction Act should not be sent to OMB.

Background

The primary mission of OFAC is to administer and enforce economic sanctions against targeted foreign countries and regimes, terrorists and terrorist organizations, weapons of mass destruction proliferators, narcotic traffickers, and others in furtherance of U.S. national security, foreign policy, and economic objectives. OFAC acts under Presidential national emergency powers, as well as specific legislation, to prohibit transactions and block (or ''freeze'') assets subject to U.S. jurisdiction. Economic sanctions are designed to deprive the target of the use of its assets and deny the target access to the U.S. financial system and the benefits of trade, transactions, and services involving U.S. markets, businesses, and individuals. These same authorities have also been used to protect assets subject to U.S. jurisdiction of countries subject to foreign occupation and to further important U.S. nonproliferation goals.

OFAC administers and enforces economic sanctions programs pursuant to Presidential and statutory authorities. OFAC is responsible for civil investigation and enforcement of economic sanctions violations committed by Subject Persons, as defined in the Guidelines. Where appropriate, OFAC may coordinate its investigative and enforcement activities with federal, state, local and/or foreign regulators and/or law enforcement agencies. Active enforcement of these programs is a crucial element in preserving and advancing the national security, foreign policy and economic objectives that underlie these initiatives. Penalties, both civil and criminal, serve as a deterrent to conduct that undermines or prevents these sanctions programs from achieving their various goals.

On January 29, 2003, OFAC published, as a proposed rule, generally applicable Economic Sanctions Enforcement Guidelines, as well as a proposed Appendix to the Cuban Assets Control Regulations (CACR) providing a schedule of proposed civil monetary penalties for certain violations of the CACR (Cuba Penalty Schedule). Though this proposed rule was not finalized, OFAC has used the generally applicable guidelines set forth therein as a general framework for its enforcement actions and the Cuban Penalty Schedule as a framework for the imposition of civil monetary penalties for the violations of the CACR described therein. On January 12, 2006, OFAC published, as an interim final rule, Economic Sanctions Enforcement Procedures for Banking Institutions which withdrew the January 29, 2003 proposed rule to the extent that it applied to banking institutions, as defined in the interim final rule.

On October 16, 2007, the President signed into law the International Emergency Economic Powers Enhancement Act (Enhancement Act),[3] substantially increasing the maximum penalties for violations of the International Emergency Economic Powers Act (IEEPA),[4] a principal statutory authority for most OFAC sanctions programs. The increased maximum penalty amounts set forth in the Enhancement Act, as well as its application to pending or commenced cases involving apparent violations of IEEPA, prompted the development of these new Guidelines for determining an appropriate enforcement response to apparent violations of sanctions programs enforced by OFAC (as defined in the Guidelines), and, in cases involving civil monetary penalties, for determining the amount of any civil monetary penalty. The Guidelines set forth in this interim final rule supersede the enforcement procedures for banking institutions set forth in the interim final rule of January 12, 2006, which is hereby withdrawn, as well as the proposed guidelines set forth in the proposed rule of January 29, 2003, which is also hereby withdrawn, with the exception of the Cuba Penalty Schedule. (Those withdrawn enforcement procedures and guidelines continue to apply to the categories of cases set forth in OFAC's November 27, 2007 Civil Penalties—Interim Policy.) The Guidelines set forth herein are applicable to all persons subject to any of the sanctions programs administered by OFAC. As discussed in greater detail below, OFAC requests comments on this interim final rule. The Guidelines set forth in this interim final rule are not applicable to penalty or enforcement actions by other agencies based on the same underlying course of conduct, the

[3] Pub. Law 110–96, 121 Stat. 1011 (October 16, 2007).

[4] Pub. Law 95–223, 91 Stat. 1626 (December 28, 1977).

disposition of goods seized by Customs and Border Protection, or the release of blocked property by OFAC.

The Guidelines set forth in this interim final rule are applicable to all enforcement matters currently pending before OFAC or that will come before OFAC in the future, whether such matters fall under IEEPA or any of the other statutes pursuant to which OFAC is authorized to enforce sanctions (including, but not limited to, the Trading With the Enemy Act), with the exception of (i) those categories of cases set forth in OFAC's November 27, 2007 Civil Penalties—Interim Policy and (ii) those matters addressed in the Cuba Penalty Schedule or the Service Provider Program Circular periodically issued by OFAC pursuant to the CACR. The Guidelines reflect the factors that OFAC will consider in determining the appropriate enforcement response to an apparent violation of an OFAC sanctions program, and those factors are consistent across programs. The civil penalty provisions of the Guidelines take into account the maximum penalties available under the various statutes pursuant to which OFAC is authorized to enforce its sanctions programs.

The Guidelines reflect several changes from the 2003 proposed rule and the 2006 interim final rule. First, rather than identifying ''aggravating'' and ''mitigating'' factors, the Guidelines set forth General Factors that OFAC will consider in determining an appropriate enforcement response to an apparent violation and, if a civil monetary penalty is warranted, in establishing the amount of that penalty. The General Factors reflect the considerations that OFAC believes are most critical to a determination of appropriate agency action. The move away from ''aggravating'' and ''mitigating'' factors was motivated in part by the realization that in many cases, a particular factor could be considered either aggravating or mitigating (e.g., remedial action was considered a mitigating factor in the 2003 proposed rule, while the absence of remedial action was considered an aggravating factor). Rather than list such factors as both aggravating and mitigating factors, OFAC believes it is better practice to identify the General Factors it will consider as part of a holistic consideration of the facts and circumstances of a particular case.

Second, the Guidelines provide for the issuance of either cautionary letters or findings of violation under certain circumstances, rather than the cautionary letters and warning letters provided for in the 2003 proposed rule and the evaluative letters provided for in the 2006 interim final rule. Cautionary letters reflect OFAC's enforcement response to an apparent violation when OFAC determines either that there is insufficient evidence to conclude that a violation has occurred or that a finding of violation is not warranted under the circumstances. A cautionary letter does not constitute a final agency determination that a violation has or has not occurred, but serves to place the Subject Person on notice that any such similar conduct in the future may result in a finding of violation or the imposition of a civil monetary penalty. Findings of violation are reserved for cases in which OFAC determines that a violation has occurred and considers it important to document the occurrence of a violation, but nevertheless concludes that the imposition of a civil monetary penalty is not the most appropriate enforcement response. Because a finding of violation constitutes a final agency determination that a violation has occurred, OFAC will afford the Subject Person an opportunity to respond to OFAC's determination. OFAC will give careful consideration to the appropriateness of issuing a cautionary letter or finding of violation in lieu of the imposition of a civil monetary penalty.

Third, in recognition of OFAC's position that the enhanced maximum civil penalties authorized by the Enhancement Act should be reserved for the most serious cases, the Guidelines distinguish between egregious and non-egregious civil monetary penalty cases. Egregious cases are defined as those representing the most serious sanctions violations, based on an analysis of all applicable General Factors, with substantial weight given to considerations of willfulness or recklessness, awareness of the conduct giving rise to an apparent violation, harm to sanctions program objectives, and the individual characteristics of the Subject Person. As described below, the Guidelines generally provide for significantly higher civil penalties for egregious cases. OFAC anticipates that the majority of enforcement cases will fall in the non-egregious category.

Fourth, in those cases in which the imposition of a civil monetary penalty is deemed appropriate, the Guidelines provide a new process for determining the penalty amount. This process involves first determining a base penalty amount. This base penalty amount is based on two primary considerations: (i) Whether the conduct, activity, or transaction giving rise to a violation is egregious or non-egregious and (ii) whether the case involves a voluntary self-disclosure by the Subject Person. As discussed above, egregious cases are generally subject to significantly higher penalties, a result reflected in the base penalty amount for such cases. In keeping with the previous enforcement guidelines and in recognition of the importance of voluntary self-disclosures to OFAC, the existence (or lack) of a voluntary self-disclosure is a major factor in establishing the penalty amount. The base penalty amount for a case involving a voluntary self-disclosure reflects a 50 percent or more reduction from the base penalty amount that would otherwise be applicable. As set forth in greater detail in the Guidelines themselves, once a base penalty amount is calculated based on the transaction value and egregiousness/voluntary self-disclosure factors, the amount may be adjusted upward or downward based on the other General Factors set forth in the Guidelines. The resulting amount reflects OFAC's proposed civil monetary penalty.

Pre-penalty notices issued pursuant to these Guidelines will set forth the actual civil monetary penalty that OFAC proposes to impose. Thus, the pre-penalty notice will provide a Subject Person with notice of the actual penalty that the agency deems appropriate under the circumstances, rather than merely identifying the maximum possible penalty. Subject Persons will be afforded an opportunity to respond to a pre-penalty notice with arguments and/or evidence respecting the amount of the proposed penalty, which OFAC will consider prior to issuing a final penalty notice. By adopting this approach, OFAC intends to bring greater transparency to the civil penalty process and to provide more useful notice to Subject Persons that may be subject to a civil monetary penalty.

The Guidelines also address the process for settling allegations of violations.

Although this interim final rule is effective immediately, OFAC is soliciting comments for a 60-day period with a view to improving the Guidelines. Comments are requested on all aspects of the Guidelines, but are particularly sought with respect to the following:

- Are the General Factors Affecting Administrative Action the appropriate factors the agency should consider in determining the type of enforcement response to an apparent violation, and, if a civil monetary penalty is warranted, the amount of that penalty? Are there other factors that should be identified in the Guidelines? Are there factors that should be eliminated? Are there factors that should be defined with greater specificity?

• Is the definition of an egregious case appropriate?

• Are the proposed base penalty amounts appropriate for the types of cases to which they are applicable?

• Does the new penalty process, whereby the pre-penalty notice sets forth the penalty that OFAC proposes to impose, constitute an improvement on current practice? Can the process be improved in other ways?

List of Subjects in 31 CFR Part 501

Administrative practice and procedure, Banks, Banking, Insurance, Money service business, Penalties, Reporting and recordkeeping requirements, Securities.

■ For the reasons set forth in the preamble, 31 CFR Part 501 is amended as follows:

PART 501—REPORTING, PROCEDURES AND PENALTIES REGULATIONS

■ 1. The authority citation for Part 501 is revised to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2332d, 2339B; 19 U.S.C. 3901–3913; 21 U.S.C. 1901–1908; 22 U.S.C. 287c; 22 U.S.C. 2370(a), 6009, 6032, 7205; 28 U.S.C. 2461 note; 31 U.S.C. 321(b); 50 U.S.C. 1701–1706; 50 U.S.C. App. 1–44.

■ 2. Part 501 is amended by revising Appendix A to Part 501 to read as follows:

Appendix A to Part 501—Economic Sanctions Enforcement Guidelines

Note: This appendix provides a general framework for the enforcement of all economic sanctions programs administered by the Office of Foreign Assets Control (OFAC), with the exception of those violations set forth in the proposed Appendix to the Cuban Assets Control Regulations (CACR), 31 CFR Part 515 (see 68 FR 4422, 4429 (January 29, 2003)) or in the Service Provider Program Circular periodically issued by OFAC pursuant to the CACR.

I. Definitions

A. *Apparent violation* means conduct that constitutes an actual or possible violation of U.S. economic sanctions laws, including the International Emergency Economic Powers Act (IEEPA), the Trading With the Enemy Act (TWEA), the Foreign Narcotics Kingpin Designation Act, and other statutes administered or enforced by OFAC, as well as Executive orders, regulations, orders, directives, or licenses issued pursuant thereto.

B. *Applicable schedule amount* means:

i. $1,000 with respect to a transaction valued at less than $1,000;

ii. $10,000 with respect to a transaction valued at $1,000 or more but less than $10,000;

iii. $25,000 with respect to a transaction valued at $10,000 or more but less than $25,000;

iv. $50,000 with respect to a transaction valued at $25,000 or more but less than $50,000;

v. $100,000 with respect to a transaction valued at $50,000 or more but less than $100,000;

vi. $170,000 with respect to a transaction valued at $100,000 or more but less than $170,000;

vii. $250,000 with respect to a transaction valued at $170,000 or more, except that where the applicable schedule amount as defined above exceeds the statutory maximum civil penalty amount applicable to an apparent violation, the applicable schedule amount shall equal such statutory maximum civil penalty amount.

C. *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

D. *Penalty* is the final civil penalty amount imposed in a Penalty Notice.

E. *Proposed penalty* is the civil penalty amount set forth in a Pre-Penalty Notice.

F. *Regulator* means any federal, state, local or foreign official or agency that has authority to license or examine an entity for compliance with federal, state, or foreign law.

G. *Subject Person* means an individual or entity subject to any of the sanctions programs administered or enforced by OFAC.

H. *Transaction value* means the dollar value of a subject transaction. In export and import cases, the transaction value generally will be the domestic value in the United States of the goods, technology, or services sought to be exported or imported into the United States, as demonstrated by commercial invoices, bills of lading, signed Customs declarations, or similar documents. In cases involving seizures by U.S. Customs and Border Protection (CBP), the transaction value generally will be the domestic value as determined by CBP. If the apparent violation at issue is a prohibited dealing in blocked property by a Subject Person, the transaction value generally will be the dollar value of the underlying transaction involved, such as the value of the property dealt in or the amount of the funds transfer that a financial institution failed to block or reject. Where the transaction value is not otherwise ascertainable, OFAC may consider the market value of the goods or services that were the subject of the transaction, the economic benefit conferred on the sanctioned party, and/or the economic benefit derived by the Subject Person from the transaction in determining transaction value. For purposes of these Guidelines, ''transaction value'' will not necessarily have the same meaning, nor be applied in the same manner, as that term is used for import valuation purposes at 19 CFR 152.103.

I. *Voluntary self-disclosure* means self-initiated notification to OFAC of an apparent violation by a Subject Person that has committed, or otherwise participated in, an apparent violation of a statute, Executive order, or regulation administered or enforced by OFAC, prior to the time that OFAC, or any other federal, state or local government agency or official, discovers the apparent violation or another substantially similar apparent violation. For these purposes, ''substantially similar apparent violation'' means an apparent violation that is part of a series of similar apparent violations or is related to the same pattern or practice of conduct. Notification to OFAC of an apparent violation is not a voluntary self-disclosure if: a third party is required to notify OFAC of the apparent violation or a substantially similar apparent violation because a transaction was blocked or rejected by that third party (regardless of whether or when OFAC actually receives such notice from the third party and regardless of whether the Subject Person was aware of the third party's disclosure); the disclosure includes false or misleading information; the disclosure (when considered along with supplemental information provided by the Subject Person) is materially incomplete; the disclosure is not self-initiated (including when the disclosure results from a suggestion or order of a federal or state agency or official); or, when the Subject Person is an entity, the disclosure is made by an individual in a Subject Person entity without the authorization of the entity's senior management. Responding to an administrative subpoena or other inquiry from, or filing a license application with, OFAC is not a voluntary self-disclosure. In addition to notification, a voluntary self-disclosure must include, or be followed within a reasonable period of time by, a report of sufficient detail to afford a complete understanding of an apparent violation's circumstances, and should also be followed by responsiveness to any follow-up inquiries by OFAC. (As discussed further below, a Subject Person's level of cooperation with OFAC is an important factor in determining the appropriate enforcement response to an apparent violation even in the absence of a voluntary self-disclosure as defined herein; disclosure by a Subject Person generally will result in mitigation insofar as it represents cooperation with OFAC's investigation.)

II. Types of Responses to Apparent Violations

Depending on the facts and circumstances of a particular case, an OFAC investigation may lead to one or more of the following actions:

A. *No Action.* If OFAC determines that there is insufficient evidence to conclude that a violation has occurred and/or, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the conduct or activity does not rise to a level warranting an administrative response, then no action will be taken. In those cases in which OFAC is aware that the Subject Person has knowledge of OFAC's investigation, OFAC generally will issue a letter to the Subject Person indicating that the investigation is being closed with no administrative action being taken. A no-action determination represents a final determination as to the apparent violation, unless OFAC later learns of additional related violations or other relevant facts.

B. *Request Additional Information.* If OFAC determines that additional information regarding the apparent violation is needed, it may request further information from the

Subject Person or third parties, including through an administrative subpoena issued pursuant to 31 CFR § 501.602. In the case of an institution subject to regulation where OFAC has entered into a Memorandum of Understanding (MOU) with the Subject Person's regulator, OFAC will follow the procedures set forth in such MOU regarding consultation with the regulator. Even in the absence of an MOU, OFAC may seek relevant information about a regulated institution and/or the conduct or activity constituting the apparent violation from the institution's federal, state, or foreign regulator. Upon receipt of information determined to be sufficient to assess the apparent violation, OFAC will decide, based on an analysis of the General Factors outlined in Section III of these Guidelines, whether to pursue further enforcement action or whether some other response to the apparent violation is appropriate.

C. *Cautionary Letter:* If OFAC determines that there is insufficient evidence to conclude that a violation has occurred or that a finding of violation is not warranted under the circumstances, but believes that the underlying conduct could lead to a violation in other circumstances and/or that a Subject Person does not appear to be exercising due diligence in assuring compliance with the statutes, Executive orders, and regulations that OFAC enforces, OFAC may issue a cautionary letter that conveys its concerns about the underlying conduct and/or the Subject Person's OFAC compliance policies, practices and/or procedures. A cautionary letter represents a final enforcement response to the apparent violation, unless OFAC later learns of additional related violations or other relevant facts, but does not constitute a final agency determination as to whether a violation has occurred.

D. *Finding of Violation:* If OFAC determines that a violation has occurred and considers it important to document the occurrence of a violation and, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the Subject Person's conduct warrants an administrative response but that a civil monetary penalty is not the most appropriate response, OFAC may issue a finding of violation that identifies the violation, conveys OFAC's concerns about the violation and/or the Subject Person's OFAC compliance policies, practices and/or procedures, and/or identifies the need for further compliance steps to be taken. A finding of violation represents a final enforcement response to the violation, unless OFAC later learns of additional related violations or other relevant facts, and constitutes a final agency determination that a violation has occurred. A finding of violation will afford the Subject Person an opportunity to respond to OFAC's determination that a violation has occurred.

E. *Civil Monetary Penalty.* If OFAC determines that a violation has occurred and, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the Subject Person's conduct warrants the imposition of a monetary penalty, OFAC may impose a civil monetary penalty. Civil monetary penalty amounts will be determined as discussed in Section V of these Guidelines. The imposition of a civil monetary penalty constitutes a final agency determination that a violation has occurred and represents a final civil enforcement response to the violation.

F. *Criminal Referral.* In appropriate circumstances, OFAC may refer the matter to appropriate law enforcement agencies for criminal investigation and/or prosecution. Apparent sanctions violations that OFAC has referred for criminal investigation and/or prosecution also may be subject to OFAC civil penalty or other administrative action.

G. *Other Administrative Actions.* In addition to or in lieu of other administrative actions, OFAC may also take the following administrative actions in response to an apparent violation:

1. *License Denial, Suspension, Modification, or Revocation.* OFAC authorizations to engage in a transaction (including the release of blocked funds) pursuant to a general or specific license may be withheld, denied, suspended, modified, or revoked in response to an apparent violation.

2. *Cease and Desist Order.* OFAC may order the Subject Person to cease and desist from conduct or activities that are prohibited by any of the sanctions programs enforced by OFAC when OFAC has reason to believe that a Subject Person has engaged in such conduct or activities and/or that such conduct or activities are ongoing or may recur.

III. General Factors Affecting Administrative Action

The type of enforcement action undertaken by OFAC will depend on the nature of the apparent violation and the harm caused to the relevant sanctions program and its objectives. As a general matter, OFAC will consider some or all of the following General Factors in determining the appropriate administrative action in response to an apparent violation of U.S. sanctions by a Subject Person, and, where a civil monetary penalty is imposed, in determining the appropriate amount of any such penalty:

A. *Willful or Reckless Violation of Law:* a Subject Person's willfulness or recklessness in violating, attempting to violate, conspiring to violate, or causing a violation of the law. Generally, to the extent the conduct, activity or transaction at issue is the result of willful misconduct or a deliberate intent to violate, attempt to violate, conspire to violate, or cause a violation of the law, the OFAC enforcement response will be stronger. Among the factors OFAC may consider in evaluating willfulness or recklessness are:

1. *Willfulness.* Was the conduct at issue the result of a decision to take action with the knowledge that such action would constitute a violation of U.S. law? Did the Subject Person know that the underlying conduct constituted, or likely constituted, a violation of U.S. law at the time of the conduct?

2. *Recklessness.* Did the Subject Person demonstrate reckless disregard for U.S. sanctions requirements or otherwise fail to exercise a minimal degree of caution or care in avoiding conduct, activities or transactions that led to the apparent violation? Were there warning signs that should have alerted the Subject Person that an action or failure to act would lead to an apparent violation?

3. *Concealment.* Was there an effort by the Subject Person to hide or purposely obfuscate its conduct, activities or transactions in order to mislead OFAC, federal, state or foreign regulators, or other parties involved in the transaction/conduct about an apparent violation?

4. *Pattern of Misconduct.* Was the apparent violation the result of a pattern or practice of conduct or was it relatively isolated and atypical in nature?

5. *Prior Notice.* Was the Subject Person on notice, or should it reasonably have been on notice, that the conduct at issue, or similar conduct, constituted a violation of U.S. law?

6. *Management Involvement.* In cases of entities, at what level within the organization did the willful or reckless misconduct occur? Were supervisory or managerial level staff aware, or should they reasonably have been aware, of the willful or reckless misconduct?

B. *Awareness of Conduct at Issue:* The Subject Person's awareness of the conduct, activity or transaction giving rise to the apparent violation. Generally, the greater a Subject Person's actual knowledge of, or reason to know about, the conduct, activity, or transaction constituting an apparent violation, the stronger the OFAC enforcement response will be. In the case of a corporation, awareness will focus on supervisory or managerial level staff in the business unit at issue, as well as other senior officers and managers. Among the factors OFAC may consider in evaluating the Subject Person's awareness of the conduct at issue are:

1. *Actual Knowledge.* Did the Subject Person have actual knowledge that the conduct, activity, or transaction giving rise to an apparent violation took place? Was the conduct, activity, or transaction part of a business process, structure or arrangement that was designed or implemented with the intent to prevent or shield the Subject Person from having such actual knowledge, or was the conduct, activity, or transaction part of a business process, structure or arrangement implemented for other legitimate reasons that made it difficult or impossible for the Subject Person to have actual knowledge?

2. *Reason to Know.* If the Subject Person did not have actual knowledge that the conduct, activity, or transaction took place, did the Subject Person have reason to know, or should the Subject Person reasonably have known, based on all readily available information and with the exercise of reasonable due diligence, that the conduct, activity, or transaction would or might take place?

3. *Management Involvement.* In the case of an entity, was the conduct, activity or transaction undertaken with the explicit or implicit knowledge of senior management, or was the conduct, activity, or transaction undertaken by personnel outside the knowledge of senior management? If the apparent violation was undertaken without the knowledge of senior management, was there oversight intended to detect and prevent violations, or did the lack of knowledge by senior management result from disregard for its responsibility to comply with applicable sanctions laws?

C. *Harm to Sanctions Program Objectives:* The actual or potential harm to sanctions program objectives caused by the conduct, activities, or transactions giving rise to the apparent violation. Among the factors OFAC may consider in evaluating the harm to sanctions program objectives are:

1. *Economic or Other Benefit to the Sanctioned Individual, Entity, or Country:* The economic or other benefit conferred or attempted to be conferred to sanctioned individuals, entities, or countries as a result of an apparent violation, including the number, size, and impact of the transactions or incidents constituting an apparent violation(s), the length of time over which they occurred, and the nature of the economic or other benefit conferred. OFAC may also consider the causal link between the Subject Person's conduct and the economic benefit conferred or attempted to be conferred.

2. *Implications for U.S. Policy:* The effect that the circumstances of the apparent violation had on the integrity of the U.S. sanctions program and the related policy objectives involved.

3. *License Eligibility:* Whether the conduct constituting the apparent violation likely would have been licensed by OFAC under existing licensing policy.

4. *Humanitarian activity:* Whether the conduct at issue was in support of a humanitarian activity.

D. *Individual Characteristics:* The particular circumstances and characteristics of a Subject Person. Among the factors OFAC may consider in evaluating individual characteristics are:

1. *Commercial Sophistication:* The commercial sophistication and experience of the Subject Person. Is the Subject Person an individual or an entity? If an individual, was the transaction constituting the apparent violation conducted for personal or business reasons?

2. *Size of Operations and Financial Condition:* The size of a Subject Person's business operations and overall financial condition may be considered, where such information is available and relevant. Qualification of the Subject Person as a small business or organization for the purposes of the Small Business Regulatory Enforcement Fairness Act, as determined by reference to the applicable regulations of the Small Business Administration, may also be considered.

3. *Volume of Transactions:* The total volume of transactions undertaken by the Subject Person on an annual basis, with attention given to the apparent violations as compared with the total volume.

4. *Sanctions Violation History:* The Subject Person's history of sanctions violations, including OFAC's issuance of prior findings of violations or cautionary, warning or evaluative letters, or other administrative actions.

E. *Compliance Program:* The existence and nature of a Subject Person's OFAC compliance program at the time of the apparent violation, where relevant. In the case of an institution subject to regulation where OFAC has entered into a Memorandum of Understanding (MOU) with the Subject Person's regulator, OFAC will follow the procedures set forth in such MOU regarding consultation with the regulator with regard to the quality and effectiveness of the Subject Person's compliance program. Even in the absence of an MOU, OFAC may take into consideration the views of federal, state, or foreign regulators, where relevant.

F. *Remedial Response:* The Subject Person's corrective action taken in response to the apparent violation. Among the factors OFAC may consider in evaluating the remedial response are:

1. The steps taken by the Subject Person upon learning of the apparent violation. Did the Subject Person immediately stop the conduct at issue?

2. In the case of an entity, the processes followed to resolve issues related to the apparent violation. Did the Subject Person discover necessary information to ascertain the causes and extent of the apparent violation, fully and expeditiously? Where applicable, were the Audit Committee and the Board of Directors fully informed? If so, when?

3. In the case of an entity, whether the Subject Person adopted new and more effective internal controls and procedures to prevent a recurrence of the apparent violation. If the Subject Person did not have an OFAC compliance program in place at the time of the apparent violation, did it implement one upon discovery or notification of the violations? If it did have an OFAC compliance program, did it take appropriate steps to enhance the program to prevent the recurrence of similar violations? Did the entity provide the individual(s) responsible for the apparent violation with additional training, and/or take other appropriate action, to ensure that similar violations do not occur in the future?

4. Where applicable, whether the Subject Person undertook a thorough review to identify other possible violations.

G. *Cooperation with OFAC:* The nature and extent of the Subject Person's cooperation with OFAC. Among the factors OFAC may consider in evaluating cooperation with OFAC are:

1. Did the Subject Person voluntarily self-disclose the apparent violation to OFAC?

2. Did the Subject Person provide OFAC with all relevant information regarding an apparent violation (whether or not voluntarily self-disclosed)?

3. Did the Subject Person research and disclose to OFAC relevant information regarding any other apparent violations caused by the same course of conduct?

4. Was information provided voluntarily or in response to an administrative subpoena?

5. Did the Subject Person cooperate with, and promptly respond to, all requests for information?

6. Did the Subject Person agree to a statute of limitations waiver or tolling agreement, if requested by OFAC (particularly in situations where the apparent violations were not immediately notified to or discovered by OFAC)?

H. *Timing of apparent violation in relation to imposition of sanctions:* The timing of the apparent violation in relation to the adoption of the applicable prohibitions, particularly if the apparent violation took place soon after relevant changes in the sanctions program regulations or the addition of a new name to OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List).

I. *Other enforcement action:* Other enforcement actions taken by federal, state, or local agencies against the Subject Person for the apparent violation or similar apparent violations, including whether the settlement of alleged violations of OFAC regulations is part of a comprehensive settlement with other federal, state, or local agencies.

J. *Future Compliance/Deterrence Effect:* The impact administrative action may have on promoting future compliance with U.S. economic sanctions by the Subject Person and similar Subject Persons, particularly those in the same industry sector.

K. *Other relevant factors on a case-by-case basis:* Such other factors that OFAC deems relevant on a case-by-case basis in determining the appropriate enforcement response and/or the amount of any civil monetary penalty. OFAC will consider the totality of the circumstances to ensure that its enforcement response is proportionate to the nature of the violation.

IV. Civil Penalties for Failure to Furnish Information or Keep Records

Except in the instance of authorized service providers under the Cuban Assets Control Regulations, for whom enforcement guidelines appear in the Service Provider Program Circular periodically issued by OFAC, as a general matter the following civil penalty amounts shall apply to a Subject Person's failure to furnish information or maintain records:

A. The failure to respond to a requirement to furnish information pursuant to 31 CFR 501.602, or failure to furnish the requested information, may result in a penalty in an amount up to $20,000, irrespective of whether any other violation is alleged. Where OFAC has reason to believe that the apparent violation(s) that is the subject of the request to furnish information involves a transaction(s) valued at greater than $500,000, a failure to respond to a request to furnish information or failure to furnish the requested information may result in a penalty in an amount up to $50,000, irrespective of whether any other violation is alleged. A failure to respond to a requirement to furnish information or a failure to furnish the requested information shall be considered a continuing violation, and the penalties described above may be imposed each month that a party has continued to fail to respond or to furnish the requested information. OFAC may also seek to have a requirement to furnish information judicially enforced. Imposition of a civil monetary penalty for failure to respond to a requirement to furnish information or a failure to furnish the requested information does not preclude OFAC from seeking such judicial enforcement.

B. The late filing of a required report, whether set forth in regulations or in a specific license, may result in a civil monetary penalty in an amount up to $2,500, if filed within the first 30 days after the report is due, and a penalty in an amount up

to $5,000 if filed more than 30 days after the report is due. If the report relates to blocked assets, the penalty may include an additional $1,000 for every 30 days that the report is overdue, up to five years.

C. The first failure to maintain records in conformance with the requirements of OFAC's regulations or of a specific license may result in a penalty in an amount up to $5,000. Each additional violation in this regard may result in a penalty in an amount up to $10,000.

V. Civil Penalties

OFAC will review the facts and circumstances surrounding an apparent violation and apply the General Factors for Taking Administrative Action in Section III above in determining whether to initiate a civil penalty proceeding and in determining the amount of any civil monetary penalty. OFAC will give careful consideration to the appropriateness of issuing a cautionary letter or finding of violation in lieu of the imposition of a civil monetary penalty.

A. Civil Penalty Process

1. *Pre-Penalty Notice.* If OFAC has reason to believe that a violation of U.S. sanctions has occurred and that a civil monetary penalty is warranted, it will issue a Pre-Penalty Notice in accordance with the procedures set forth in the particular regulations governing the conduct, activity, or transactions giving rise to the apparent violation. The amount of the proposed penalty set forth in the Pre-Penalty Notice will reflect OFAC's preliminary assessment of the appropriate penalty amount, based on information then in OFAC's possession. The amount of the final penalty may change as OFAC learns additional relevant information. If, after issuance of a Pre-Penalty Notice, OFAC determines that a penalty in an amount that represents an increase of more than 10 percent from the proposed penalty set forth in the Pre-Penalty Notice is appropriate, or if OFAC intends to allege additional violations, it will issue a revised Pre-Penalty Notice setting forth the new proposed penalty amount and/or alleged violations.

a. In general, the Pre-Penalty Notice will set forth the following with respect to the specific violations alleged and the proposed penalties:

i. Description of the alleged violations, including the number of violations and their value, for which a penalty is being proposed;

ii. Identification of the regulatory or other provisions alleged to have been violated;

iii. Identification of the General Factors that were most relevant to the determination of the proposed penalty amount, including the base category (defined below) according to which the proposed penalty amount was calculated;

iv. The maximum amount of the penalty to which the Subject Person could be subject under applicable law; and

v. The proposed penalty amount, determined in accordance with the provisions set forth in these Guidelines.

b. The Pre-Penalty Notice will also include information regarding how to respond to the Pre-Penalty Notice including:

i. A statement that the Subject Person may submit a written response to the Pre-Penalty Notice by a date certain addressing the alleged violation(s), the General Factors Affecting Administrative Action set forth in Section III of these Guidelines, and any other information or evidence that the Subject Person deems relevant to OFAC's consideration.

ii. A statement that a failure to respond to the Pre-Penalty Notice likely will result in the imposition of a civil monetary penalty in the amount set forth in the Pre-Penalty Notice.

2. *Response to Pre-Penalty Notice.* A Subject Person may submit a written response to the Pre-Penalty Notice in accordance with the procedures set forth in the particular regulations governing the conduct, activity or transactions giving rise to the apparent violation. Generally, the response should either agree to the proposed penalty set forth in the Pre-Penalty Notice or set forth reasons why a penalty should not be imposed or, if imposed, why it should be a lesser amount than proposed, with particular attention paid to the General Factors Affecting Administrative Action set forth in Section III of these Guidelines. The response should include all documentary or other evidence available to the Subject Person that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted.

3. *Penalty Notice.* If OFAC receives no response to a Pre-Penalty Notice within the time prescribed in the Pre-Penalty Notice, or if following the receipt of a response to a Pre-Penalty Notice and a review of the information and evidence contained therein OFAC concludes that a violation warranting a civil monetary penalty has occurred, a Penalty Notice generally will be issued in accordance with the procedures set forth in the particular regulations governing the conduct, activity or transactions giving rise to the violation. A Penalty Notice constitutes a final agency finding that a violation has occurred. The penalty amount set forth in the Penalty Notice will take into account relevant additional information provided in response to a Pre-Penalty Notice. In the absence of a response to a Pre-Penalty Notice, the penalty amount set forth in the Penalty Notice will generally be the same as the proposed penalty set forth in the Pre-Penalty Notice.

4. *Referral to Financial Management Division.* The imposition of a civil monetary penalty pursuant to a Penalty Notice creates a debt due the U.S. Government. OFAC will advise Treasury's Financial Management Division upon the imposition of a penalty. The Financial Management Division may take follow-up action to collect the penalty assessed if it is not paid within the prescribed time period set forth in the Penalty Notice. In addition or instead, the matter may be referred to the U.S. Department of Justice for appropriate action to recover the penalty.

5. *Final Agency Action.* The imposition of a penalty pursuant to a Penalty Notice constitutes final agency action with respect to the violation(s) for which the penalty is assessed.

B. Amount of Civil Penalty

1. *Egregious case.* In those cases in which a civil monetary penalty is deemed appropriate, OFAC will make a determination as to whether a case is deemed ''egregious'' for purposes of the base penalty calculation. This determination will be based on an analysis of the applicable General Factors. In making the egregiousness determination, OFAC generally will give substantial weight to General Factors A (''willful or reckless violation of law''), B (''awareness of conduct at issue''), C (''harm to sanctions program objectives'') and D (''individual characteristics''), with particular emphasis on General Factors A and B. A case will be considered an ''egregious case'' where the analysis of the applicable General Factors, with a focus on those General Factors identified above, indicates that the case represents a particularly serious violation of the law calling for a strong enforcement response. A determination that a case is ''egregious'' will be made by the Director or Deputy Director.

2. *Pre-Penalty Notice.* The penalty amount proposed in a Pre-Penalty Notice shall generally be calculated as follows, except that neither the base amount nor the proposed penalty will exceed the applicable statutory maximum amount:

a. Base category calculation

i. In a non-egregious case, if the apparent violation is disclosed through a voluntary self-disclosure by the Subject Person, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be one-half of the transaction value, capped at a maximum base amount of $125,000 per violation.

ii. In a non-egregious case, if the apparent violation comes to OFAC's attention by means other than a voluntary self-disclosure, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be the ''applicable schedule amount,'' as defined above (capped at a maximum base amount of $250,000 per violation).

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure by a Subject Person, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be one-half the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OFAC's attention by means other than a voluntary self-disclosure, the base amount of the proposed civil monetary penalty in the Pre-Penalty Notice shall be the statutory maximum penalty amount applicable to the violation.

The following matrix represents the base amount of the proposed civil penalty for each category of violation:

		Egregious Case	
		NO	YES
Voluntary Self-Disclosure	YES	(1) One-Half of Transaction Value (capped at $125,000 per violation)	(3) One-Half of Statutory Maximum
	NO	(2) Applicable Schedule Amount (capped at $250,000 per violation)	(4) Statutory Maximum

The base penalty amount will not exceed the applicable statutory maximum amount.

b. Adjustment for applicable relevant General Factors

The base amount of the proposed civil penalty may be adjusted to reflect applicable General Factors for Administrative Action set forth in Section III of these Guidelines. Each factor may be considered mitigating or aggravating, resulting in a lower or higher proposed penalty amount. As a general matter, in those cases where the following General Factors are present, OFAC will adjust the base proposed penalty amount in the following manner:

i. In cases involving substantial cooperation with OFAC but no voluntary self-disclosure as defined herein, including cases in which an apparent violation is reported to OFAC by a third party but the Subject Person provides substantial additional information regarding the apparent violation and/or other related violations, the base penalty amount generally will be reduced between 25 and 40 percent. Substantial cooperation in cases involving voluntary self-disclosure may also be considered as a further mitigating factor.

ii. In cases involving a Subject Person's first violation, the base penalty amount generally will be reduced up to 25 percent. The extent of any such mitigation will be based, in part, on whether the Subject Person had previously been issued a cautionary, warning or evaluative letter.

In all cases, the proposed penalty amount will not exceed the applicable statutory maximum.

In cases involving a large number of apparent violations, where the transaction value of all apparent violations is either unknown or would require a disproportionate allocation of resources to determine, OFAC may estimate or extrapolate the transaction value of the total universe of apparent violations in determining the amount of any proposed civil monetary penalty.

3. *Penalty Notice.* The amount of the proposed civil penalty in the Pre-Penalty Notice will be the presumptive starting point for calculation of the civil penalty amount in the Penalty Notice. OFAC may adjust the penalty amount in the Penalty Notice based on:

a. Evidence presented by the Subject Person in response to the Pre-Penalty Notice, or otherwise received by OFAC with respect to the underlying violation(s); and/or

b. Any modification resulting from further review and reconsideration by OFAC of the proposed civil monetary penalty in light of the General Factors for Administrative Action in Section III above.

In no event will the amount of the civil monetary penalty in the Penalty Notice exceed the proposed penalty set forth in the Pre-Penalty Notice by more than 10 percent, or include additional alleged violations, unless a revised Pre-Penalty Notice has first been sent to the Subject Person as set forth above. In the event that OFAC determines upon further review that no penalty is appropriate, it will so inform the Subject Person in a no-action letter, a cautionary letter, or a finding of violation.

C. Settlements

A settlement does not constitute a final agency determination that a violation has occurred.

1. *Settlement Process.* Settlement discussions may be initiated by OFAC, the Subject Person or the Subject Person's authorized representative. Settlements generally will be negotiated in accordance with the principles set forth in these Guidelines with respect to appropriate penalty amounts. OFAC may condition the entry into or continuation of settlement negotiations on the execution of a tolling agreement with respect to the statute of limitations.

2. *Settlement Prior to Issuance of Pre-Penalty Notice.* Where settlement discussions occur prior to the issuance of a Pre-Penalty Notice, the Subject Person may request in writing that OFAC withhold issuance of a Pre-Penalty Notice pending the conclusion of settlement discussions. OFAC will generally agree to such a request as long as settlement discussions are continuing in good faith and the statute of limitations is not at risk of expiring.

3. *Settlement Following Issuance of Pre-Penalty Notice.* If a matter is settled after a Pre-Penalty Notice has been issued, but before a final Penalty Notice is issued, OFAC will not make a final determination as to whether a sanctions violation has occurred. In the event no settlement is reached, the period specified for written response to the Pre-Penalty Notice remains in effect unless additional time is granted by OFAC.

4. *Settlements of Multiple Apparent Violations.* A settlement initiated for one apparent violation may also involve a

comprehensive or global settlement of multiple apparent violations covered by other Pre-Penalty Notices, apparent violations for which a Pre-Penalty Notice has not yet been issued by OFAC, or previously unknown apparent violations reported to OFAC during the pendency of an investigation of an apparent violation.

Dated: September 2, 2008.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. E8–20704 Filed 9–5–08; 8:45 am]

BILLING CODE 4811–45–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0290]

RIN 1625–AA00

Safety Zone; Gulf of Mexico—Johns Pass, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Johns Pass, Florida while construction operations are being conducted. This rule is necessary to ensure the safety of the workers and mariners on the navigable waters of the United States. No person or vessel may anchor, moor, or transit the Regulated Area without permission of the Captain of the Port St. Petersburg, Florida.

DATES: This safety zone will be effective August 29, 2008 through August 30, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2008–0290 and are available online at *http://www.regulations.gov*. This material is also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and Coast Guard Sector St Petersburg Prevention Department, 155 Columbia Dr., Tampa, FL 33606 between 7:30 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call BM1 Charles Voss at Coast Guard Sector St. Petersburg, (813) 228–2191 Ext 8307. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On May 29, 2008 we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Gulf of Mexico—Johns Pass, FL in the **Federal Register**, 73 FR 30868. We did not receive any letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

Flatiron Construction will be performing construction work on the new Johns Pass Bridge. This work will involve setting girders, installing a new fendering system, setting the deck, setting overhangs, placing resteel, pouring the bridge deck, and wrecking the old bridge's deck. These operations will require the closure of the navigable channel. The closures will only be for limited times, during nighttime hours, and scheduled to accommodate the local marine traffic. The nature of the operation and environment surrounding the Johns Pass Bridge presents a danger to the workers and mariners transiting the area. This proposed safety zone is being established to ensure the safety of life on the navigable waters of the United States.

Discussion of Comments and Changes

No comments were received for this rule and no changes were made to the proposed rule text.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary.

The rule will only be enforced during a time when vessel traffic is expected to be minimal. Moreover, vessels may still enter the safety zone with the express permission of the Captain of the Port St. Petersburg or a designated representative.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit Johns Pass, FL. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be enforced for a limited time when marine traffic is expected to be minimal; additionally traffic will be allowed to enter the zone with the permission of the Captain of the Port Sector St. Petersburg or a designated representative.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM, we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

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

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded under the Instruction that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T08–0290 is added to read as follows:

§ 165.T08–290 Safety Zone; Gulf of Mexico—Johns Pass, Florida.

(a) *Regulated area.* The Coast Guard is establishing a temporary safety zone on the waters of the Gulf of Mexico, Florida, in the vicinity of the John's Pass Bridge, that includes all the waters from surface to bottom, within a 100-yard radius of the following coordinates: 27°46′58″ N,082°46′57″ W. All coordinates referenced use datum: NAD 83.

(b) *Definitions.* The following definition applies to this section:

Designated representative means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the Captain of the Port (COTP) St. Petersburg, Florida, in the enforcement of regulated navigation areas and safety and security zones.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, no person or vessel may anchor, moor or transit the Regulated Area without the prior permission of the Captain of the Port St. Petersburg, Florida, or a designated representative.

(d) *Dates.* This rule is effective until the bridge construction is completed tentatively scheduled for July 2010.

(e) *Enforcement.* This regulated area will only be enforced while construction operations are taking place. The Coast Guard does not know the exact dates of the construction operations at this time, however Sector St. Petersburg will announce each enforcement period by publishing the restriction in the local notice to mariners and issuing Broadcast Notice to Mariners 24 to 48 hours prior to the start of enforcement. Additionally, on-scene notice will be provided by Coast Guard or other local law enforcement maritime units enforcing the safety zone.

Dated: August 6, 2008.

T.M. Close,

Captain, U.S. Coast Guard, Captain of the Port, St. Petersburg.

[FR Doc. E8–20481 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–15–P

Proposed Rules

Federal Register
Vol. 73, No. 174
Monday, September 8, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 302, 330, 335, 337, and 410

RIN 3206–AL04

Recruitment, Selection, and Placement (General)

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) is proposing to revise the rules on Federal vacancy announcements, reemployment priority list requirements, positions restricted to preference eligibles, time after competitive appointment, the Career Transition Assistance Plan (CTAP), and the Interagency Career Transition Assistance Plan (ICTAP). The proposed rules clarify the regulations, incorporate longstanding OPM policies, revise placement assistance programs for consistency and effectiveness, remove references to two expired interagency placement assistance programs, and reorganize information for ease of reading.

DATES: We will consider comments received on or before November 7, 2008.

ADDRESSES: Send or deliver comments to Angela Bailey, Deputy Associate Director, Center for Talent and Capacity Policy, Strategic Human Resources Policy, U.S. Office of Personnel Management, Room 6551, 1900 E Street, NW., Washington, DC 20415–9700; e-mail to *employ@opm.gov*; or fax to (202) 606–2329. Comments may also be sent through the Federal eRulemaking Portal at *http://www.regulations.gov.* All submissions received through the Portal must include the agency name and docket number or the Regulation Identifier Number (RIN) for this rulemaking. Please specify the subpart and section number for each comment.

FOR FURTHER INFORMATION CONTACT: For subparts A, D, and E, contact Linda Watson by telephone at (202) 606–0830; TTY at (202) 418–3134; fax at (202) 606–0390; or e-mail at *linda.watson@opm.gov.* For all other subparts, contact Pam Galemore by telephone at (202) 606–0960; TTY at (202) 418–3134; fax at (202) 606–2329; or e-mail at *pamela.galemore@opm.gov.*

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) is proposing to revise the regulations in 5 CFR part 330 governing Federal vacancy announcements, the Reemployment Priority List (RPL), positions restricted to preference eligibles, time after competitive appointment, the Career Transition Assistance Plan (CTAP), and the Interagency Career Transition Assistance Plan (ICTAP). The proposed revisions are described below under each subpart heading.

The proposed regulations also remove subparts K and L. Subpart K provided a priority consideration program for eligible displaced employees of the District of Columbia Department of Corrections. The statutory authority for this program expired on December 31, 2002. Subpart L provided selection priority to eligible displaced employees in the Panama Canal Zone. The statutory authority for this program expired on December 31, 2000.

Throughout the proposed regulations, OPM has replaced the verb ''shall'' with ''must'' for clarity. OPM intends that any provisions in this part using the verb ''must'' have the same meaning and effect as previous provisions in this part using ''shall.''

These proposed regulations also include conforming changes in parts 302—Employment in the Excepted Service, 335—Promotion and Internal Placement, 337—Examining System, and 410—Training of OPM's regulations, specifically to revise citations because of the movement of the rules governing vacancy announcements from subpart G to subpart A.

Subpart A

We are proposing to retitle Subpart A from ''Discretion in Filling Vacancies'' to ''Filling Vacancies in the Competitive Service'' to more accurately reflect the content of the subpart. The proposed revised subpart A includes a list of specific items that must be included in all vacancy announcements published on OPM's USAJOBS Web site (which is the official job site for the Federal Government). Subpart A also adds requirements mandated by the Veterans Employment Opportunities Act, which is codified in part at 5 U.S.C. 3304(f)(4). These proposed changes will support the requirement for specific information in the vacancy announcement and establish consistency in the information provided to applicants. OPM's authority to require items in a vacancy announcement is in 5 U.S.C. 3330.

We are proposing to add definitions in § 330.101 and move the paragraph about ''agencies covered'' currently in § 330.102 to § 330.101. These revisions consolidate definitions that are applicable throughout part 330, and define *vacancy* solely for the purposes of subpart A in accordance with 5 U.S.C. 3327.

Under 5 U.S.C. 3330, OPM is required to keep a current list of all competitive service vacancy announcements for which agencies will accept applications from outside their respective workforces. Currently, subpart G of part 330, which covers the Interagency Career Transition Assistance Plan (ICTAP), contains OPM's regulations prescribing information that agencies must include in Federal vacancy announcements (such as title, location, duties, etc.). We are proposing to move this information from subpart G, § 330.707, to subpart A, § 330.104, because the reporting requirement applies to all competitive service vacancy announcements. Conforming revisions to other CFR parts with the reference to § 330.707 are included with these proposed regulations.

OPM receives inquiries on a regular basis from agencies concerning how to add a vacancy announcement to OPM's USAJOBS Web site. We propose to add in § 330.105 that agencies may locate these instructions on the Web site at www.usajobs.opm.gov.

Subpart B

Subpart B governs the Reemployment Priority List (RPL), which is the program an agency must use to meet its statutory reemployment priority obligations under sections 3315 and 8151 of title 5, United States Code. Agencies establish an RPL to provide selection priority to their permanent competitive service employees who were or will be involuntarily separated through reduction in force (RIF) procedures under part 351, or who have recovered from a compensable work-related injury after more than 1 year, as required by 5

CFR 353.301(b). These employees may register for, and receive selection priority over, most other candidates from outside the agency's current permanent competitive service workforce. Agencies must apply veterans' preference when making RPL placements.

Generally, the proposed revisions to subpart B clarify who is eligible for the RPL, delete references to outdated material (e.g., appointment authorities that no longer exist), and clarify the operation of the RPL through use of plain language and improved organization of the material.

We are also proposing to define and rename certain terms (e.g., ''priority consideration'' to ''placement priority'') to clearly distinguish the RPL program from other internal agency placement programs. The proposed regulations also clarify longstanding OPM policy concerning employees' rights, agency flexibility, and termination of eligibility.

Other proposed revisions to subpart B include the following:

Section 330.202 adds a ''Definitions'' section for terms used throughout the subpart. This section includes a definition of *Qualified* for RPL purposes. The proposed definition ensures that placement of the RPL registrant will not detract or hinder mission accomplishment by requiring that, for RPL placement priority, the placement of the RPL registrant in the position will not cause an undue interruption to required work. The undue interruption provision is currently provided as an exception to the RPL selection order in § 330.207. Adding this provision as part of the *Qualified* definition makes the qualifications required for placement through the RPL consistent with those required for placement through RIF procedures. Also for consistency, the term ''selection placement factors'' is revised to ''selective factors'' to align with terminology used in OPM's ''Operating Manual: Qualification Standards for General Schedule Positions.''

Revised § 330.203 combines the conditions for RPL eligibility based on recovery from a compensable injury, currently in § 330.204, with RPL eligibility based on a notice of or actual RIF separation. Section 330.203(a)(2) clarifies that RPL eligibility ends if the employee receives a written notice of cancellation, rescission, or modification to the official notice which established RPL eligibility (for example, the agency cancels the employee's notice of RIF separation or the agency offers a position with a representative rate at least as high as that of the position from which the employee will be separated). In § 330.203(a)(3), we are proposing to raise the minimum performance rating of record level required for RIF-based RPL eligibility from a rating above unacceptable (Level 1) to at least fully successful (Level 3) or equivalent. (The proposed definition of *Rating of record* in § 330.202 corresponds to the definition in part 351 to cover those cases where an appraisal system does not have a summary rating level of fully successful.) The proposed change makes the rating of record required for RIF-based RPL eligibility consistent with the minimum performance rating of record required for selection priority under both the Career Transition Assistance Plan (CTAP) in subpart F and the Interagency Career Transition Assistance Plan (ICTAP) in subpart G. A minimum rating of record is not required for RPL eligibility based on recovery from a compensable work-related injury.

Section 330.204(b) adds a requirement for agencies to provide information about the agency's RPL program to each RPL eligible employee when the employee accepts a position at a lower grade or pay level or separates from the agency because of a compensable work-related injury. This provision is added to ensure employees are informed of their rights under 5 U.S.C. 8151.

Section 330.206(a)(3) revises the period for an employee with RPL eligibility because of a RIF to apply for the agency's RPL. The current regulation in § 330.202(a)(1) requires the employee to apply within 30 calendar days after the RIF separation date. We propose to require that RPL eligibles must apply on or before the RIF separation date. The proposed change is intended to ease the administrative burden on agencies while allowing a RIF-based RPL eligible at least 60 days (the minimum notice period under part 351) to apply for registration. We are not proposing to change the application period for RPL eligibles based on recovery from a compensable work injury.

Section 330.207 clarifies and expands agency discretion for RPL registration areas. Specifically, § 330.207(b) allows an agency the discretion to register an employee in a local commuting area other than the local commuting area from which the employee will be, or has been, separated if the agency does not, or will not, have any competitive service positions remaining in the local commuting area from which the employee will be, or has been, separated. This provision addresses closure situations that are not currently covered in the regulations.

The proposed § 330.207(d) requires an agency to establish a fair and consistent policy for expanding the registration area for an employee whose RPL eligibility is based on recovery from a compensable work injury. The current regulation in § 330.206(b) requires an agency to determine when and how to provide for maximum opportunities for consideration; however, it does not require an agency to establish a policy for making such determinations.

The proposed § 330.207(e) deletes Alaska from the current § 330.206(a)(4), concerning RPL eligibility for overseas positions; Alaska does not meet the definition of ''overseas'' in part 210 of this chapter.

Section 330.208 changes the period and expiration date of RPL eligibility from the current period in § 330.203(c) of 2 years from the date of RPL registration for a tenure group I eligible and 1 year from the date of RPL registration for a tenure group II eligible. To ease the administrative burden on agencies and to maximize placement priority under this program, we propose to change the period and expiration date for RPL eligibility for both tenure groups to 2 years from the date of separation by RIF, or from the date of registration if eligibility is based on recovery from a compensable work injury. We also propose to add a provision that OPM may extend the eligibility period when an RPL eligible is not timely registered, for example, due to an administrative or procedural error. The current regulations do not specifically provide OPM with this authority. Adding this provision will avoid having to consider such an extension through a regulatory variation under Civil Service Rule 5.1 (5 CFR 5.1).

Section 330.209(a)(2) clarifies that an RPL registrant is removed from the RPL if the registrant receives a written notice of cancellation, rescission, or modification to the official notice which established RPL eligibility (for example, the agency cancels the employee's notice of RIF separation or the agency offers a position with a representative rate at least as high as that of the position from which the employee will be separated).

Sections 330.209(a)(5) and (6) clarify that RPL eligibility ends when the RPL registrant is actually placed in or appointed to a different position rather than when the registrant ''receives'' an appointment as currently described in § 330.203(d)(2)(ii).

Section 330.210(a) clarifies that RPL placement priority applies to permanent and time-limited positions to be filled by competitive service appointment.

Section 330.211(a) clarifies that an agency may fill vacancies with candidates from within its permanent competitive service workforce without regard to the RPL, after the agency meets its CTAP obligations under subpart F of part 330.

Paragraphs (d) and (e) of § 330.213 add an alternative rating and selection procedure (also called category rating) and an application-based procedure, respectively, to provide agencies with additional referral and selection methods. The category rating procedure is derived from 5 U.S.C. 3319, as implemented in 5 CFR part 337 and OPM's ''Delegated Examining Operations Handbook.'' The application-based procedure is similar to the employee-empowerment model established under CTAP and ICTAP procedures in subparts F and G of this part, respectively.

The proposed regulation also deletes current paragraph (c) of § 330.208 concerning agency consideration of sex in determining qualifications for the RPL; this consideration is part of the qualification requirements.

Subpart C remains reserved.

Subpart D

We are proposing to revise §§ 330.401 through 330.403 to clarify that the statutory restriction of certain positions to preference eligibles applies to any competitive examination, regardless of whether OPM or an agency, through delegated authority under 5 U.S.C. 1104(a)(2), performs the examination. We also specify exceptions to the restriction and include a staffing procedure inadvertently omitted during OPM's process of deleting references in the Code of Federal Regulations to the Federal Personnel Manual (FPM) because of its sunset. We propose to retitle § 330.401 as ''Restricted Positions.'' This section identifies the restricted positions covered in 5 U.S.C. 3310. Definitions of these positions are located in OPM's Delegated Examining Operations Handbook at *http://www.opm.gov/deu.*

We are proposing to retitle § 330.402 as ''Exceptions to Restriction.'' Section 330.402 identifies the types of appointments an agency may use when filling a restricted position with a nonpreference eligible. Agencies will be required to obtain OPM's approval prior to making a selection if the type of appointment is not identified in § 330.402.

We are proposing to retitle § 330.403 as ''Positions Brought into the Competitive Service.'' This section includes a staffing procedure formerly described in the FPM. Under this section, agencies will be able to convert the appointment of a nonpreference eligible whose restricted position was brought into the competitive service.

Subpart E

We are proposing to revise this subpart for readability, to delete a reference to a part-time direct hire program that no longer exists, and to renumber the sections accordingly.

Subparts F and G

Since the 1940s, and in addition to the statutory RPL, the Federal Government has had placement assistance programs to help its permanent workforce transition to other positions when employees have been adversely affected by reorganizations, reshaping, or contracting-out of work. These programs support both the Government as a whole and specific agency missions by preserving the investment in high-quality, well-trained, experienced employees.

In 1994, Congress directed OPM to study competitive service placement programs to determine a better Governmentwide approach than the centralized, list-based programs in use at the time. OPM developed CTAP and ICTAP in 1995 in conjunction with agencies, labor organizations, Federal Executive Boards, employees, and other stakeholders.

The CTAP (which applies in the employee's current agency) and the ICTAP (which applies to agencies other than the employee's current or last agency) established under subparts F and G, respectively, provide selection priority to employees displaced from their jobs through no fault of their own. Under CTAP and ICTAP, instead of the centralized listings that were used in the past, eligible employees apply directly for agency vacancies and receive selection priority only if they are determined to be well-qualified for the position under the agency's job-related evaluation criteria.

Throughout subparts F and G, we are proposing to delete duplication and outdated references, to incorporate longstanding OPM policies and guidance, to clarify the material by using plain language, and to reorganize the subparts for ease of use. The proposed revisions clarify the difference between an employee eligible to apply under CTAP and ICTAP versus an employee eligible to receive selection priority under these plans. The proposed revision also clarifies that excepted service appointments are exempt from CTAP and ICTAP selection priority, which is limited to competitive service appointments. With this in mind, we are proposing to revise the definition of *agency* in § 330.101 to include entities with positions in the competitive service by statute or Executive order, which is not clear under the current definitions in subparts F and G.

We are also proposing to replace the term ''directed reassignment'' with ''directed geographic relocation'' in both subparts. This change clarifies that declination of any management-directed involuntary movement to a different commuting area (e.g., reassignment or change in duty station) establishes eligibility for CTAP and ICTAP selection priority.

Through these proposed regulations, we are also inviting comments concerning the exceptions to CTAP and ICTAP selection priority. Currently, there are numerous exceptions to applying CTAP and ICTAP selection priority under subparts F and G, respectively. We are interested in stakeholders' views on the number and types of exceptions as well as additional exceptions that may be considered necessary for efficient and effective use of agency workforces. When replying to this invitation, please indicate the rationale behind proposing to delete or add specific exceptions.

Subpart F

The following are specific proposed revisions within subpart F:

Section 330.601(c) is revised to delete the specific reference to the Department of Defense exemption from certain portions of the CTAP regulations. The revision also provides the same flexibility for agencies to develop their own internal placement assistance programs as is available under the RPL regulations in subpart B.

Section 330.602 is revised to delete definitions that have been consolidated in the proposed subpart A and to add definitions for *CTAP eligible* and *CTAP selection priority candidate* to clarify the difference between these two terms. The definition of *Displaced* is revised to add a provision that the employee must not have declined a RIF offer under part 351, subpart G, to a position with the same type of work schedule and a representative rate at least as high as that of the position from which the employee will be separated. Adding this provision makes CTAP eligibility consistent with RPL eligibility criteria. In addition, the proposed regulations move the criteria for agency definitions of ''well-qualified'' from the definitions section to a separate section, § 330.606. Each agency is responsible for defining ''well-qualified'' for the purposes of its CTAP, and the revised § 330.606

prescribes the minimum requirements for agency definitions. Because ''well-qualified'' is an agency-defined term, the minimum criteria for the agency definition are more appropriate in the regulatory text. We have also deleted from the well-qualified criteria the statement, ''Selective and quality ranking factors cannot be so restrictive that they run counter to the goal of placing displaced employees'' as unnecessary. Selective factors and quality ranking factors must be developed through job analysis and be job-related in accordance with 5 CFR part 300. OPM provides guidance on developing these factors in the ''Delegated Examining Operations Handbook.''

Section 330.606(c) adds a provision that an agency may include the results of a scored structured interview process to determine whether a CTAP eligible is well-qualified when such a process is used to assess the qualified candidates being considered for the vacancy. Many agencies now use a scored interview as an assessment tool in addition to the initial evaluation of qualified candidates' applications against job-related criteria for rating and ranking purposes. Adding this provision clarifies that the results of this tool can be used in determining whether candidates are well-qualified. This provision is also proposed for addition to § 330.704(c).

Section 330.607(b) clarifies the provision in the current regulations at § 330.606(a) concerning procuring temporary help services. The clarification states that agencies must make a determination under part 300, subpart E, that CTAP eligibles are not available before procuring temporary help services under that subpart. This provision is also proposed for addition to § 330.706(b).

Section 330.608(a) adds an option for agencies to provide the required CTAP orientation session in person or through the agency's automated training system or Intranet.

Section 330.609 moves the list of exceptions to CTAP selection priority from current § 330.606(d) to a separate section for easier reference.

Section 330.609(y) (current paragraph (26) of § 330.606) clarifies an unintentional difference between CTAP and ICTAP under subpart G which allows program exceptions for extensions of time-limited promotions and appointments, including OPM-approved extensions. We are clarifying that OPM-approved exceptions are covered under subpart G.

Section 330.609(dd) adds an exception to CTAP selection priority to include placements made under 5 CFR part 412, Senior Executive Service merit staffing procedures for developmental programs. This exception is also added at § 330.707(v).

Section 330.611(a) clarifies that, to establish selection priority, a CTAP eligible must submit all required materials and eligibility documentation within the timeframe established by the agency. The wording of the current regulation in § 330.605(a)(5) implies that proof of eligibility does not have to be submitted within agency-established timeframes, which was not the intent. This clarification is also proposed for addition to § 330.709(a).

Subpart G

In addition to the proposed revisions discussed under ''Subparts F and G'' above, the following are specific proposed revisions within subpart G.

Section 330.701 deletes outdated material and clarifies that ICTAP selection priority applies only in agencies other than the employee's current or former agency. The CTAP and RPL programs provide selection and placement priority, respectively, in the employee's current or former agency.

Section 330.702 is revised to delete definitions that have been consolidated in the proposed subpart A and to revise the definition of *Displaced*. Specifically, the proposed revision deletes ''A former career or career-conditional competitive service employee, in tenure group 1 or 2, at grades GS–15 level or equivalent or below, who received a RIF separation notice, and who retired on the effective date of the RIF or under discontinued service retirement option.'' from the current definition in § 330.703(b)(5). This provision had the unintentional result of providing ICTAP selection priority to employees who left the employing agency before the agency effected the RIF action. We are proposing to delete this provision to make ICTAP selection priority consistent with the other placement assistance programs covered under this part that provide selection priority to employees whose agency has taken an action. Also, employees may receive an offer of continued employment during a RIF notice period.

The revised definition of *Displaced* in § 330.702 also adds a provision that the employee must not have declined a RIF offer under part 351, subpart G, to a position with the same type of work schedule and a representative rate at least as high as that of the position from which the employee was, or will be, separated. Adding this provision makes ICTAP eligibility consistent with RPL eligibility criteria.

We added definitions for *ICTAP eligible* and *ICTAP selection priority candidate* to clarify the difference between these two terms.

As discussed under subpart F, we moved the criteria for agency definitions of ''well-qualified'' from the definitions section to a separate section, § 330.704, because each agency is responsible for defining ''well-qualified'' for the purposes of its ICTAP, and the revised § 330.704 prescribes the minimum requirements for agency definitions. Because ''well-qualified'' is an agency-defined term, the minimum criteria for the agency definition are more appropriate in the regulatory text.

Section 330.704(c) adds a provision that an agency may include the results of a scored structured interview process to determine whether an ICTAP eligible is well-qualified when such a process is used to assess the qualified candidates being considered for the vacancy. As discussed under subpart F above, many agencies now use a scored interview as an assessment tool in addition to the initial evaluation of qualified candidates' applications against job-related criteria for rating and ranking purposes. Adding this provision clarifies that the results of this tool can be used in determining whether candidates are well-qualified. This provision is also proposed for addition to § 330.606(c).

Section 330.705(d)(2) adds provisions for an agency to make additional selections or reissue selection certificates without re-determining whether potential ICTAP eligibles are available within the local commuting area. Under the current regulations, an agency must determine if ICTAP eligibles are available whenever it makes a selection that is not an authorized exception to ICTAP. The proposed § 330.705(d)(2) allows agencies to make additional selections or reissue a selection certificate from an applicant pool previously established by a vacancy announcement under which ICTAP eligibles had an opportunity to apply.

Section 330.705(f) adds a provision that an agency may deny an ICTAP eligible future selection priority for a position previously obtained through ICTAP if the eligible was terminated or removed for cause (e.g., for performance under 5 CFR part 432 or under adverse actions procedures under 5 CFR part 752) from that position. This could occur if the ICTAP eligible was placed in a temporary position.

Section 330.707 moves the list of exceptions to ICTAP selection priority from current § 330.705(b) to a separate section for easier reference. As

discussed earlier under subpart A, we are also proposing to revise and move the information concerning agency requirements for reporting vacancies to OPM from the current regulation at § 330.707 to subpart A.

Section 330.707(v) adds an exception to ICTAP to include placements made under 5 CFR part 412, Senior Executive Service merit staffing procedures for developmental programs. This exception is also added at § 330.609(dd).

Section 330.708 clarifies when ICTAP eligibility expires, depending on the basis for the eligibility. This clarification addresses inconsistencies in the interpretation of exactly when ICTAP eligibility expires. For example, some agencies provide selection priority for the duration of the selection process, meaning until a selection is made, even though the 1-year period of ICTAP eligibility may have expired during that process. OPM's intent was always to have a definitive eligibility cut-off date, consistent with the other placement assistance programs covered by this part. Agencies retain the option to select a displaced employee whose ICTAP eligibility has expired under the reinstatement authority provided by 5 CFR 315.401.

We also propose to add a provision in § 330.708(e) that OPM may extend the eligibility period when a displaced employee does not receive timely information on ICTAP eligibility or another administrative or procedural error occurs that adversely impacts the eligibility period. The current regulations do not specifically provide OPM with this authority. Adding this provision will avoid having to consider such an extension through a regulatory variation under Civil Service Rule 5.1 (5 CFR 5.1).

Section 330.709(a) clarifies that, to establish selection priority, an ICTAP eligible must submit all required materials and eligibility documentation within the timeframe established by the agency. The wording of the current regulation in § 330.704(a)(5) implies that proof of eligibility does not have to be submitted within agency established timeframes, which was not the intent. This clarification is also proposed for addition to § 330.611(a).

Subparts H and I remain reserved.

Subpart J is unchanged.

Subparts K and L

We are proposing to remove these subparts, which provided special selection priority to certain displaced employees of the District of Columbia Department of Corrections and Panama Canal Zone, respectively. As explained above, the statutory authority for these programs has expired.

For the convenience of the reader, the proposed part 330 is published in its entirety.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects

5 CFR Parts 302, 335, and 337

Government employees.

5 CFR Part 330

Armed forces reserves, District of Columbia, Government employees.

5 CFR Part 410

Education, Government employees.

Office of Personnel Management.

Michael W. Hager,

Acting Director.

Accordingly, OPM proposes to amend 5 CFR parts 302, 330, 335, 337, and 410 as follows:

PART 302—EMPLOYMENT IN THE EXCEPTED SERVICE

1. The authority citation for part 302 continues to read as follows:

Authority: 5 U.S.C. 1302, 3301, 3302, 8151, E.O. 10577 (3 CFR 1954–1958 Comp., p. 218); § 302.105 also issued under 5 U.S.C. 1104, Pub. L. 95–454, sec. 3(5); § 302.501 also issued under 5 U.S.C. 7701 *et seq.*

§ 302.106 [Amended]

2. In § 302.106, remove the phrase ''§ 330.707 of subpart G'' and add in its place the phrase, ''part 330, subpart A''.

3. Revise part 330 to read as follows:

PART 330—RECRUITMENT, SELECTION, AND PLACEMENT (GENERAL)

Subpart A—Filling Vacancies in the Competitive Service

Sec.
330.101 Definitions.
330.102 Methods of filling vacancies.
330.103 Requirement to notify OPM.
330.104 Required items for a vacancy announcement.
330.105 Instructions on how to add a vacancy announcement to USAJOBS.
330.106 Funding.

Subpart B—Reemployment Priority List (RPL)

330.201 Purpose.
330.202 Definitions.
330.203 RPL eligibility.
330.204 Agency requirements and responsibilities.
330.205 Agency RPL applications.
330.206 RPL registration timeframe and positions.
330.207 Registration area.
330.208 Duration of RPL registration.
330.209 Removal from an RPL.
330.210 Applying RPL placement priority.
330.211 Exceptions to RPL placement priority.
330.212 Agency flexibilities.
330.213 Selection from an RPL.
330.214 Appeal rights.

Subpart C—[Reserved]

Subpart D—Positions Restricted to Preference Eligibles

330.401 Restricted positions.
330.402 Exceptions to restriction.
330.403 Positions brought into the competitive service.
330.404 Displacement of preference eligibles occupying restricted positions in contracting out situations.
330.405 Agency placement assistance.
330.406 OPM placement assistance.
330.407 Eligibility for the Interagency Career Transition Assistance Plan.

Subpart E—Restrictions to Protect Competitive Principles

330.501 Purpose.
330.502 General restriction on movement after competitive appointment.
330.503 Ensuring agency compliance with the principles of open competition.
330.504 Exception to the general restriction.

Subpart F—Agency Career Transition Assistance Plans (CTAP) for Local Surplus and Displaced Employees

330.601 Purpose.
330.602 Definitions.
330.603 Requirements for agency CTAPs.
330.604 Requirements for agency CTAP selection priority.
330.605 Agency responsibilities for well-qualified decisions.
330.606 Minimum criteria for agency well-qualified definition.
330.607 Applying CTAP selection priority.
330.608 Other agency CTAP responsibilities.
330.609 Exceptions to CTAP selection priority.
330.610 CTAP eligibility period.
330.611 Establishing CTAP selection priority.
330.612 Proof of eligibility.
330.613 OPM's role in CTAP.

Subpart G—Interagency Career Transition Assistance Plan (ICTAP) for Displaced Employees

330.701 Purpose.
330.702 Definitions.
330.703 Agency responsibilities for well-qualified decisions.
330.704 Minimum criteria for agency well-qualified definition.
330.705 Applying ICTAP selection priority.
330.706 Other agency ICTAP responsibilities.

330.707 Exceptions to ICTAP selection priority.
330.708 ICTAP eligibility period.
330.709 Establishing ICTAP selection priority.
330.710 Proof of eligibility.
330.711 OPM's role in ICTAP.

Subparts H–I—[Reserved]

Subpart J—Prohibited Practices

330.1001 Withdrawal from competition.

Subparts K–L—[Reserved]

Authority: 5 U.S.C. 105, 1104, 1302, 3301, 3302, 3304, and 3330; E.O. 10577, 3 CFR, 1954–58 Comp., p. 218.

Section 330.102 also issued under 5 U.S.C. 3327. Subpart B also issued under 5 U.S.C. 3315 and 8151. Section 330.401 also issued under 5 U.S.C. 3310. Subpart G also issued under 5 U.S.C. 8337(h) and 8456(b).

Subpart A—Filling Vacancies in the Competitive Service

§ 330.101 Definitions.

In this part:

Agency means:

(1) The executive departments listed at 5 U.S.C. 101;

(2) The military departments listed at 5 U.S.C. 102;

(3) Government owned corporations in the executive branch as described at 5 U.S.C. 103;

(4) Independent establishments in the executive branch as described at 5 U.S.C. 104, including the Nuclear Regulatory Commission; and

(5) Government Printing Office.

Component means the first major subdivision of an agency, separately organized, and clearly distinguished in work function and operation from other agency subdivisions, e.g., the Internal Revenue Service under the Department of the Treasury or the National Park Service under the Department of the Interior.

Local commuting area is defined in part 351 of this chapter.

Permanent competitive service workforce and *permanent competitive service employees* mean agency employees in career and career conditional appointments, tenure groups I and II, respectively.

Position change is defined in part 210 of this chapter.

Rating of record is defined in part 351 of this chapter.

Representative rate is defined in part 351 of this chapter.

Tenure groups are defined in part 351 of this chapter.

In this subpart:

Vacancy means a vacant position in the competitive service, regardless of whether the position will be filled by permanent or time-limited appointment, for which an agency is seeking applications from outside its current permanent competitive service workforce.

§ 330.102 Methods of filling vacancies.

An agency may fill a vacancy in the competitive service by any method authorized in this chapter, including competitive appointment from a list of eligibles, noncompetitive appointment under special authority, reinstatement, transfer, reassignment, change to lower grade, or promotion. The agency must exercise discretion in each personnel action solely on the basis of merit and fitness, without regard to political or religious affiliation, marital status, or race, and veterans' preference entitlements.

§ 330.103 Requirement to notify OPM.

An agency must notify OPM promptly when:

(a) Filling a vacancy for more than 120 days from outside the agency's current permanent competitive service workforce, as required by the Interagency Career Transition Assistance Plan, subpart G of this part, unless the action to be taken is listed in subpart G as an exception to that subpart;

(b) Filling any vacancy under the agency's merit promotion procedures when the agency will accept applications from outside its permanent competitive service workforce; and

(c) Filling a vacancy by open competitive examination, including direct hire procedures under part 337 of this chapter, or in the Senior Executive Service, as required by 5 U.S.C. 3327.

§ 330.104 Required items for a vacancy announcement.

(a) The vacancy announcement must contain the following information:

(1) Name of issuing agency;

(2) Announcement number;

(3) Position title, series, pay plan, and grade (or pay rate);

(4) Duty location;

(5) Number of vacancies;

(6) Opening date and application deadline (closing date), plus any other information dealing with how application receipt will be controlled, such as the use of early cut-off dates, received, or postmarked date;

(7) Qualification requirements, including knowledge, skills, and abilities or competencies;

(8) Starting pay;

(9) Brief description of duties;

(10) Basis of rating;

(11) What to file;

(12) Instructions on how to apply;

(13) Information on how to claim veterans' preference, if applicable;

(14) Definition of ''well-qualified,'' as required by subparts F and G of this part;

(15) Information on how candidates eligible under subparts F and G of this part may apply, including required proof of eligibility;

(16) Contact person or contact point;

(17) Equal employment opportunity statement (OPM recommends using the following statement: ''The United States Government does not discriminate in employment on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, marital status, disability, age, membership in an employee organization, or other non-merit factor''); and

(18) Reasonable accommodation statement.

(b)(1) An agency may use wording of its choice in its statement that conveys the availability of reasonable accommodation required by § 330.104(a)(18). In its reasonable accommodation statement, an agency may not list types of medical conditions or impairments appropriate for accommodation.

(2) OPM recommends using the following statement:

''This agency provides reasonable accommodation to applicants with disabilities where appropriate. If you need a reasonable accommodation for any part of the application and hiring process, please notify the agency. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.''

§ 330.105 Instructions on how to add a vacancy announcement to USAJOBS.

An agency can find the instructions to add a vacancy announcement to USAJOBS on OPM's Web site at *http://www.usajobs.opm.gov.* An electronic file of the complete vacancy announcement must be included.

§ 330.106 Funding.

Each year, OPM will charge a fee for the agency's share of the cost of providing employment information to the public and to Federal employees as authorized by 5 U.S.C. 3330(f).

Subpart B—Reemployment Priority List (RPL)

§ 330.201 Purpose.

(a) The Reemployment Priority List (RPL) is a required component of agency placement programs to assist its current and former competitive service employees who will be or were separated by reduction in force (RIF) under part 351 of this chapter, or who have recovered from a compensable work-related injury after more than 1

year, as required by part 353 of this chapter. In filling vacancies, an agency must give its RPL registrants placement priority for most competitive service vacancies before hiring someone from outside its own permanent competitive service workforce. An agency may choose to consider RPL placement priority candidates before other agency permanent competitive service employees under its Career Transition Assistance Plan (CTAP) established under subpart F of this part, after fulfilling agency obligations to its CTAP selection priority candidates.

(b) Agencies must use an RPL to give placement priority to their:

(1) Current competitive service employees with a specific notice of RIF separation or a Certification of Expected Separation issued under part 351 of this chapter;

(2) Former competitive service employees separated by RIF under part 351 of this chapter; and

(3) Former competitive service employees fully recovered from a compensable injury (as defined in part 353 of this chapter) after more than 1 year.

(c) All agency components within the local commuting area use a single RPL and are responsible for giving placement priority to the agency's RPL registrants.

(d) With prior OPM approval, an agency may operate an alternate placement program which satisfies the basic requirements of this subpart, including veterans' preference, as an exception to the RPL regulations under this subpart. This provision is limited to reemployment priority because of RIF separation and allows agencies to adopt different placement strategies that are effective for their programs and satisfy employee entitlements to reemployment priority.

§ 330.202 Definitions.

In this subpart:

Competitive area is defined in part 351 of this chapter.

Competitive service appointment includes new appointments, reinstatements, reemployment, and transfers as defined in part 210 of this chapter, and conversions as defined in OPM's ''Guide to Processing Personnel Actions.''

Injury, in relation to the RPL, is defined in part 353 of this chapter.

Overseas is defined in part 210 of this chapter.

Qualified refers to an RPL registrant who:

(1) Meets OPM-established or -approved qualification standards and requirements for the position, including minimum educational requirements, and agency-established selective factors (as this term is used in OPM's ''Operating Manual: Qualification Standards for General Schedule Positions'');

(2) Will not cause an undue interruption that would prevent the completion of required work by the registrant 90 days after the registrant is placed in the position (This 90-day standard should be considered within the allowable limits of time and quality, taking into account the pressures of priorities, deadlines, and other demands.);

(3) Is physically qualified, with or without reasonable accommodation, to perform the duties of the position;

(4) Meets any special OPM-approved qualifying conditions for the position; and

(5) Meets any other applicable requirements for competitive service appointment.

RPL eligible means a current or former employee of the agency who meets the conditions in either paragraph (a) or (b) of § 330.203. As used in this subpart, ''RPL eligible'' and ''eligible'' are synonymous.

RPL placement priority candidate means an RPL registrant who is qualified and available for a specific agency vacancy.

RPL registrant means an RPL eligible who submitted a timely RPL application and who is registered on the agency's RPL. As used in this subpart, ''RPL registrant'' and ''registrant'' are synonymous.

Vacancy means any vacant position to be filled by a competitive service permanent or time-limited appointment.

§ 330.203 RPL eligibility.

An employee must meet the conditions in either paragraph (a) or (b) of this section to be an RPL eligible.

(a) For eligibility based on part 351 of this chapter, the employee:

(1) Must be serving in an appointment in the competitive service in tenure group I or II;

(2) Must have received either a specific notice of separation or a Certification of Expected Separation under part 351 of this chapter that has not been cancelled, rescinded, or modified so that the employee is no longer under notice of separation;

(3) Must have received a rating of record of at least fully successful (Level 3) or equivalent as the most recent performance rating of record; and

(4) Must not have declined an offer under part 351, subpart G, of this chapter of a position with the same type of work schedule and with a representative rate at least as high as that of the position from which the employee will be separated.

(b) For eligibility based on part 353 of this chapter, the employee or former employee:

(1) Must be serving in, or separated from, an appointment in the competitive service in tenure group I or II;

(2) Must either have accepted a position at a lower grade or pay level in lieu of separation or have been separated because of a compensable injury or disability (For the purposes of this subpart, any reference to the ''position from which or will be separated'' includes the position from which the RPL eligible accepted the lower graded or pay level position under this paragraph.);

(3) Must have fully recovered more than 1 year after compensation began; and

(4) Must have received notification from the Office of Workers Compensation Programs, Department of Labor, that injury compensation benefits have ceased or will cease.

§ 330.204 Agency requirements and responsibilities.

(a) An agency must establish policies and maintain an RPL for each local commuting area in which the agency has RPL eligibles.

(b) An agency must give each RPL eligible information about its RPL program, including Merit Systems Protection Board appeal rights under § 330.214, when:

(1) The agency issues a RIF separation notice or a Certification of Expected Separation under part 351 of this chapter; or

(2) The employee accepts a position at a lower grade or pay level or is separated from the agency because of a compensable work-related injury.

(c) An agency must register an RPL eligible on the appropriate RPL no later than 10 calendar days after receiving the eligible's written application.

(d) Agencies must include in their RPL policies established under this subpart how they will assist RPL eligibles who:

(1) Request an RPL application;

(2) Request help in completing the RPL application; and

(3) Request help in identifying and listing on the RPL application those positions within the agency for which they are qualified and interested.

(e) An agency must give RPL registrants placement priority for personnel actions as described in § 330.210.

(f) An agency must not remove an individual from the RPL under § 330.209(a)(1), (b)(1), or (b)(2) without

evidence (such as a Postal Service return receipt signed by addressee only) showing that the offer, inquiry, or scheduled interview was made in writing. The written offer, inquiry, or scheduled interview must clearly state that failure to respond will result in removal from the RPL for positions at that grade or pay level and for positions at lower grades and pay levels for which registered.

§ 330.205 Agency RPL applications.

Agencies may develop their own application format which must, at a minimum:

(a) Allow an RPL eligible to register for positions at the same representative rate and work schedule (full-time, part-time, seasonal, or intermittent) as the position from which the RPL eligible was, or will be, separated; and

(b) Allow an RPL eligible to specify the conditions under which he or she will accept a position, including grades or pay levels, appointment type (permanent or time-limited), occupations (e.g., position classification series or career groups), and minimum number of hours of work per week, as applicable.

§ 330.206 RPL registration timeframe and positions.

(a) To register, an RPL eligible must:

(1) Meet the eligibility conditions under § 330.203(a) or (b);

(2) Complete an RPL application prescribed by the current or former agency and keep the agency informed of any significant changes in the information provided; and

(3) Submit the RPL application on or before the RIF separation date or, if an RPL eligible under § 330.203(b), within 30 calendar days after the:

(i) Date injury compensation benefits cease; or

(ii) Date the Department of Labor denies an appeal for continuation of injury compensation benefits.

(b) RPL eligibles may register and receive placement priority for positions for which they are qualified and that:

(1) Have a representative rate no higher than the position from which they were, or will be, separated unless the eligible was demoted as a tenure group I or II employee in a previous RIF. If the eligible was so demoted, the eligible can register for positions with a representative rate up to the representative rate of the position held on a permanent appointment immediately before the RIF demotion was effective;

(2) Have no greater promotion potential than the position from which they were, or will be, separated; and

(3) Have the same type of work schedule as the position from which they were, or will be, separated.

§ 330.207 Registration area.

(a) Except as provided in paragraphs (b) through (e) of this section, RPL registration is limited to the local commuting area in which the eligible was, or will be, separated.

(b) If the agency has, or will have, no competitive service positions remaining in the local commuting area from which the RPL eligible will be separated under part 351 of this chapter, the agency may designate a different local commuting area where there are continuing positions for the RPL eligible to exercise placement priority. The agency has sole discretion to offer this option and over which local commuting area to designate.

(c) If the RPL eligible agreed to transfer with his or her function under part 351 of this chapter but will be separated by RIF from the gaining competitive area, registration is limited to the RPL covering the gaining competitive area's local commuting area.

(d) If eligible under § 330.203(b), registration is initially limited to the RPL covering the local commuting area of the position from which the employee was separated. Agencies must establish a fair and consistent policy which permits RPL eligibles to expand their registration to available local commuting areas mutually acceptable to the RPL eligible and the agency, up to agency-wide as required by 5 U.S.C. 8151. In lieu of expanded registration, the agency policy may provide for the RPL eligible to elect to receive placement priority for the next best available position in the former local commuting area.

(e) If the RPL eligible was, or will be, separated from an overseas position (see part 301 of this chapter), RPL registration is limited to the local commuting area in which the eligible was, or will be, separated, unless:

(1) The agency approves a written request by the RPL eligible for registration in the local commuting area from which employed for overseas service, or in another area within the United States that is mutually acceptable to the eligible and the agency; or

(2) The agency has a formal program for rotating employees between overseas areas and the United States, and the RPL eligible's preceding and prospective overseas service would exceed the maximum duration of an overseas duty tour in the rotation program. In this case, the eligible may register for a local commuting area within the United States that is mutually acceptable to the eligible and the agency.

§ 330.208 Duration of RPL registration.

(a) RPL registration expires 2 years from the date of separation under part 351 of this chapter, or 2 years from the date the agency registers the RPL eligible under § 330.206(a)(3)(i) or (ii), unless the registrant is removed from the RPL for a reason specified in § 330.209.

(b) OPM may extend the registration period when an RPL eligible does not receive a full 2 years of placement priority, for example, because of administrative or procedural error.

§ 330.209 Removal from an RPL.

(a) An RPL registrant is removed from the RPL at all registered grades or pay levels if the registrant:

(1) Declines or fails to reply to the agency's inquiry about an RPL offer of a career, career-conditional, or excepted appointment without time limit for a position having the same type of work schedule and a representative rate at least as high as the position from which the registrant was, or will be, separated;

(2) Receives a written cancellation, rescission, or modification to:

(i) The RIF separation notice or Certification of Expected Separation so that the employee no longer meets the conditions for RPL eligibility in § 330.203(a); or

(ii) The notification of cessation of injury compensation benefits so that injury compensation benefits continue;

(3) Separates from the agency for any other reason (such as retirement, resignation, or transfer) before the RIF separation effective date. Registration continues if the RPL registrant retires on or after the RIF separation effective date. This paragraph does not apply to an RPL registrant under § 330.203(b);

(4) Requests the agency to remove his or her name from the RPL;

(5) Is placed in a position without time limit at any grade or pay level within the agency;

(6) Is placed in a position under a career, career-conditional, or excepted appointment without time limit at any grade or pay level in any agency; or

(7) Leaves the area covered by an overseas RPL (see 5 CFR part 301) or is ineligible for continued overseas employment because of previous service or residence.

(b) An RPL registrant is removed from the RPL at registered grades or pay levels with a representative rate at and below the representative rate of a position offered by the agency if the offered position is below the last grade or pay level held and the registrant:

(1) Declines or fails to reply to the agency's inquiry about an RPL offer of a career, career-conditional, or excepted appointment without time limit for a position meeting the acceptable conditions shown on the RPL registrant's application; or

(2) Declines or fails to appear for a scheduled interview.

(c) An RPL registrant removed from the RPL under paragraph (b) of this section at lower grade(s) or pay level(s) than the last grade or pay level held remains on the RPL for positions with a representative rate higher than the offered position up to the grade or pay level last held, unless registration expires or otherwise terminates.

(d) Declination of time-limited employment does not affect RPL eligibility.

§ 330.210 Applying RPL placement priority.

(a) RPL placement priority applies to:

(1) Permanent and time-limited positions to be filled by competitive service appointment; and

(2) The grade or pay level at which the agency fills the position. If a position is available at multiple grades or pay levels, placement priority applies at the grade or pay level at which the position is ultimately filled.

(b) An agency must not effect a permanent or time-limited competitive service appointment of another individual if there is an RPL placement priority candidate registered for the vacancy, unless the action is listed as an exception in § 330.211.

(c) An agency must document that there are no RPL placement priority candidates for the vacancy when requesting a competitive certificate of eligibles under part 332 of this chapter. Similarly, an agency must offer the vacancy to any RPL placement priority candidate(s) before effecting an appointment under a noncompetitive appointing authority, such as under part 315 of this chapter.

(d) Once an agency has ensured there are no RPL placement priority candidates for a particular vacancy and documents in writing an employment offer that is accepted by another individual, the agency may fulfill that employment offer to that individual.

§ 330.211 Exceptions to RPL placement priority.

An agency may effect the following personnel actions as exceptions to § 330.210:

(a) Fill a vacancy with an employee of the agency's current permanent competitive service workforce through detail or position change, subject to the requirements of subpart F of this part;

(b) Appoint a 10-point preference eligible through an appropriate appointing authority;

(c) Appoint a current or former employee exercising restoration rights under part 353 of this chapter based on return from military service or recovery from a compensable injury or disability within 1 year;

(d) Appoint a current or former employee exercising other statutory or regulatory reemployment rights;

(e) Fill a specific position when all RPL placement priority candidates decline an offer of the position or fail to respond to a written agency inquiry about their availability;

(f) Convert an employee serving under an appointment that provides noncompetitive conversion eligibility to a competitive service appointment, including from:

(1) A Veterans Recruitment Appointment under part 307 of this chapter;

(2) An appointment under 5 U.S.C. 3112 and part 316 of this chapter of a veteran with a compensable service-connected disability of 30 percent or more; and

(3) An excepted service appointment under part 213 of this chapter, such as for persons with disabilities or in the Presidential Management Fellow Program, the Student Career Experience Program, or the Federal Career Intern Program;

(g) Reappoint without a break in service to the same position currently held by an employee serving under a temporary appointment of 1 year or less (only to another temporary appointment not to exceed 1 year or less);

(h) Extend an employee's temporary or term appointment up to the maximum permitted by the appointment authority or as authorized by OPM; or

(i) Appoint an individual under an excepted service appointing authority.

§ 330.212 Agency flexibilities.

An agency may provide the following flexibilities within its written RPL policies established under this subpart:

(a) Allow RPL eligibles to register only for certain sub-areas of a local commuting area when the agency has components dispersed throughout a large commuting area. However, an agency cannot deny registration throughout the local commuting area if the RPL eligible requests it.

(b) Suspend an RPL registration for all positions, permanent and time-limited, if the agency is unable, through documented written means, to contact the RPL registrant; however, the agency must reactivate an RPL registration when the registrant submits an updated application or otherwise requests reactivation in writing. Registration suspension and reactivation do not change the expiration date of the original registration period set in § 330.208.

(c)(1) Modify the OPM or OPM-approved qualification standard used to determine if an RPL eligible is qualified for a position, provided the:

(i) Exception is applied consistently and equitably in filling a position;

(ii) RPL registrant meets any minimum educational requirements for the position; and

(iii) RPL registrant has the capacity, adaptability, and special skills needed to satisfactorily perform the duties and responsibilities of the position, as determined by the agency.

(2) Any modification to the qualification standard under paragraph (c)(1) of this section does not authorize a waiver of the selection order required under § 330.210.

(d) Permit RPL eligibles to register for positions with work schedules different from the work schedule of the position from which they were, or will be, separated.

(e) Permit RPL registrants to update their qualifications or conditions for accepting positions during the RPL registration period. If adopted, the agency must update the RPL registrant's registration information within 10 calendar days of receipt of the registrant's written request. The updated registration information would apply only to those vacancies becoming available after the agency updates the RPL registrant's registration.

§ 330.213 Selection from an RPL.

(a) *Methods.* An agency must adopt one of the selection methods in paragraphs (b), (c), or (d) of this section for a single RPL. The agency may adopt the same method for each RPL it establishes or may vary the method by location, but it must adopt a written policy for each RPL it establishes and maintains. While an agency may not vary the method used for an individual vacancy, it may at any time change the selection method for all positions covered by a single RPL.

(b) *Retention standing order.* For each vacancy to be filled, the agency places qualified RPL placement priority candidates in tenure group and subgroup order in accordance with part 351 of this chapter. In making a selection, an agency may not pass over a candidate in tenure group I to select from tenure group II and, within a tenure group, may not pass over a candidate in a higher subgroup to select

from a lower subgroup. Within a subgroup, an agency may select any candidate without regard to order of retention standing.

(c)(1) *Numerical scoring*. For each vacancy to be filled, the agency rates RPL placement priority candidates according to their job experience and education. The agency must use job-related evaluation criteria for the position to be filled that is capable of distinguishing differences in qualifications measured and must apply the criteria in a fair and consistent manner. The agency assigns the candidates a numerical score of at least 70 on a scale of 100, based on the evaluation criteria developed under this paragraph. The agency must grant 5 additional points to veterans' preference eligibles under 5 U.S.C. 2108(3)(A) and (B), and 10 additional points to veterans' preference eligibles under 5 U.S.C. 2108(3)(C) through (G).

(2) RPL placement priority candidates with an eligible numerical score are ranked in the following order:

(i) Veterans' preference eligibles having a compensable service-connected disability of 10 percent or more in the order of their augmented ratings, unless the position to be filled is a professional or scientific position at or above the GS–9 level, or equivalent; and

(ii) All other candidates in the order of their augmented ratings. At each score, candidates entitled to 10 point veterans' preference will be entered ahead of all other candidates, and those entitled to 5 point veterans' preference will be entered ahead of those candidates not entitled to veterans' preference.

(3) The agency must make its selection from among the highest three candidates available and may not pass over a veterans' preference eligible to select a nonpreference eligible.

(d) *Alternative rating and selection*. (1) For each vacancy to be filled, the agency may use alternative rating (also called category rating) as described in 5 U.S.C. 3319 and part 337 of this chapter. The agency assesses RPL placement priority candidates against job-related evaluation criteria and then places them into two or more pre-defined quality categories.

(2) To use this method, the agency must:

(i) Establish a system for evaluating RPL placement priority candidates that provides for two or more quality categories;

(ii) Define each quality category through job analysis conducted in accordance with the ''Uniform Guidelines on Employee Selection Procedures'' at 29 CFR part 1607 and part 300 of this chapter. Each quality category must have a clear definition that distinguishes it from other quality categories; and

(iii) Place candidates into the appropriate quality categories based upon their job-related competencies, knowledge, skills, and abilities.

(3) Veterans' preference must be applied as prescribed in 5 U.S.C. 3319(b) and (c)(2). Veterans' preference points as prescribed in paragraph (c)(1) of this section are not applied under this method.

(4) The agency must make its selection from the highest quality category.

(e) *Application-based procedure*. (1) An agency may adopt an application-based procedure which allows RPL registrants to apply directly for RPL placement priority under an advertised vacancy announcement. Before using this procedure, the agency must establish policies and procedures for:

(i) Informing RPL registrants of available vacancies;

(ii) Informing RPL registrants of acceptable application formats, including how to permanently change initial registration information and how to apply changes only to the specific vacancy announcement for which the application is made;

(iii) Determining the method under which the RPL registrant will be rated and ranked (paragraph (b), (c), or (d) of this section); and

(iv) Informing each RPL registrant who applies under this method whether he or she was determined to be an RPL placement priority candidate and the outcome of the selection process, if the candidate was referred for selection.

(2) RPL registrants may not be removed from the RPL for failure to apply for a vacancy under this paragraph. Registration continues until it expires or the registrant is removed from the RPL under § 330.209.

§ 330.214 Appeal rights.

An RPL registrant who believes the agency violated his or her reemployment rights under this subpart by employing another person who otherwise could not have been appointed properly may appeal to the Merit Systems Protection Board under the Board's regulations.

Subpart C—[Reserved]

Subpart D—Positions Restricted to Preference Eligibles

§ 330.401 Restricted positions.

Under 5 U.S.C. 3310, competitive examinations for the positions of custodian, elevator operator, guard, and messenger (referred to in this subpart as *restricted positions*) are restricted to preference eligibles as long as a preference eligible is available. For more information on these restricted positions, refer to the OPM Delegated Examining Operations Handbook.

§ 330.402 Exceptions to restriction.

(a) An agency may fill a restricted position with a nonpreference eligible under the following circumstances:

(1) By competitive examination when no preference eligible applies;

(2) By position change (promotion, demotion, or reassignment) to a position in the organizational entity (i.e., the part of an agency from which selections are normally made for promotion or reassignment to the position in question) in which the nonpreference eligible is employed;

(3) By reemployment in the agency where the nonpreference eligible was formerly employed when he or she is being appointed from the Reemployment Priority List under subpart B of this part;

(4) By reinstatement in the agency where the nonpreference eligible was formerly employed when he or she was last separated because of disability retirement; or

(5) By reappointment of certain temporary employees as provided for in part 316 of this chapter.

(b) Except as indicated in paragraph (a) of this section, OPM must authorize any other agency noncompetitive action (*e.g.*, under an authority specified in part 315 of this chapter) to fill a restricted position with a nonpreference eligible.

§ 330.403 Positions brought into the competitive service.

An agency may convert the appointment of a nonpreference eligible whose restricted position was brought into the competitive service under part 316 of this chapter, and who meets the requirements for conversion under part 315 of this chapter, to career or career conditional appointment.

§ 330.404 Displacement of preference eligibles occupying restricted positions in contracting out situations.

An individual agency and OPM both have additional responsibilities when the agency decides, in accordance with the Office of Management and Budget (OMB) Circular A–76, to contract out the work of a preference eligible who holds a restricted position. These additional responsibilities as described in §§ 330.405 and 330.406 are applicable if a preference eligible holds a competitive service position that is:

(a) A restricted position as designated in 5 U.S.C. 3310 and § 330.401; and

(b) In tenure group I or II, as defined in § 351.501(b)(1) and (2) of this chapter.

§ 330.405 Agency placement assistance.

An agency that separates a preference eligible from a restricted position by reduction in force under part 351 of this chapter because of a contracting out situation covered in § 330.404 must, consistent with § 330.603, advise the employee of the opportunity to participate in available career transition programs. The agency is also responsible for:

(a) Applying OMB's policy directives on the preference eligible's right of first refusal for positions that are contracted out to the private sector; and

(b) Cooperating with State units as designated or created under title I of the Workforce Investment Act of 1998 to retrain displaced preference eligibles for other continuing positions.

§ 330.406 OPM placement assistance.

OPM's responsibilities include:

(a) Assisting agencies in operating positive placement programs, such as the Career Transition Assistance Plan, which is authorized by subpart F of this part;

(b) Providing interagency selection priority through the Interagency Career Transition Assistance Plan, which is authorized by subpart G of this part; and

(c) Encouraging cooperation between local Federal activities to assist these displaced preference eligibles in applying for other Federal positions, including positions with the U.S. Postal Service.

§ 330.407 Eligibility for the Interagency Career Transition Assistance Plan.

(a) A preference eligible who is separated from a restricted position by reduction in force under part 351 of this chapter because of a contracting out situation covered in § 330.404 has interagency selection priority under the Interagency Career Transition Assistance Plan, which is authorized by subpart G of this part.

(b) A preference eligible covered by this subpart is eligible for the Interagency Career Transition Assistance Plan for 2 years following separation by reduction in force from a restricted position.

Subpart E—Restrictions to Protect Competitive Principles

§ 330.501 Purpose.

The restrictions in this subpart are designed to prevent circumvention of the open competitive examination system defined in Civil Service Rule 1.3 (5 CFR 1.3). These restrictions limit an appointee's immediate movement to another position after appointment from a competitive certificate of eligibles.

§ 330.502 General restriction on movement after competitive appointment.

(a) An agency must wait at least 90 days since an employee's latest nontemporary competitive appointment before the agency may take the following actions:

(1) Promote an employee;

(2) Transfer, reinstate, reassign, or detail an employee to a different position; or

(3) Transfer, reinstate, reassign, or detail an employee to a different geographical area.

(b) Upon written request from an agency, OPM may waive the restriction against movement to a different geographical area when moving such an employee is consistent with open competition principles.

§ 330.503 Ensuring agency compliance with the principles of open competition.

OPM will review appointments made from competitive examinations and subsequent position changes to determine if agencies are complying with open competition principles. The fact that an agency waited 90 days to make the changes, as required under this subpart, is not an absolute protection. If OPM finds that an agency has not complied with these principles, either in an individual instance or on a program-wide basis, OPM will order an agency to correct the situation.

§ 330.504 Exception to the general restriction.

The restrictions in this subpart do not apply to a person who is eligible for a competitive appointment from a certificate of eligibles under part 332 of this chapter.

Subpart F—Agency Career Transition Assistance Plan (CTAP) for Local Surplus and Displaced Employees

§ 330.601 Purpose.

(a) Agency Career Transition Assistance Plans (CTAPs) provide intra-agency selection priority for its eligible surplus and displaced employees. This subpart sets forth minimum requirements for agency plans and establishes requirements for CTAP selection priority.

(b) Consistent with these regulations and at their discretion, agencies may supplement these requirements to expand career transition opportunities to their surplus and displaced workers.

(c) With prior OPM approval, an agency may operate an alternate placement program which satisfies the basic requirements of this subpart as an exception to CTAP selection priority under this subpart. This provision allows agencies to adopt different placement strategies that are effective for their programs while satisfying employee entitlements to selection priority.

§ 330.602 Definitions.

For purposes of this subpart:

CTAP eligible means an agency surplus or displaced employee who has a current performance rating of record of at least fully successful (Level 3) or equivalent. As used in this subpart, ''CTAP eligible'' and ''eligible'' are synonymous.

CTAP selection priority candidate means a CTAP eligible who applied for and was determined to be well-qualified by the agency and whom the agency must select over any other applicant for the vacancy, unless the action to be taken is listed as an exception under § 330.609.

Displaced means an agency employee in one of the following two categories:

(1) A current career or career-conditional (tenure group I or II) competitive service employee at grade GS–15 (or equivalent) or below who:

(i) Received a reduction in force (RIF) separation notice under part 351 of this chapter and has not declined an offer under part 351, subpart G, of this chapter of a position with the same type of work schedule and a representative rate at least as high as that of the position from which the employee will be separated; or

(ii) Received a notice of proposed removal under part 752 of this chapter for declining a directed geographic relocation outside of the local commuting area (e.g., a directed reassignment or change in duty station).

(2) A current excepted service employee on an appointment without time limit at grade level GS–15 (or equivalent) or below who:

(i) Is covered by a law providing both noncompetitive appointment eligibility to, and selection priority for, competitive service positions; and

(ii) Received a RIF separation notice under part 351 of this chapter or a notice of proposed removal under part 752 of this chapter for declining a directed geographic relocation outside the local commuting area (e.g., a directed reassignment or a change in duty station).

Surplus means an agency employee in one of the following three categories:

(1) A current career or career-conditional (tenure group I or II) competitive service employee at grade

GS–15 (or equivalent) or below who received a Certification of Expected Separation under part 351 of this chapter or other official agency certification or notification indicating that the employee's position is surplus (for example, a notice of position abolishment or a notice of eligibility for discontinued service retirement).

(2) A current excepted service employee on an appointment without time limit at grade GS–15 (or equivalent) or below who:

(i) Is covered by a law providing both noncompetitive appointment eligibility to, and selection priority for, competitive service positions; and

(ii) Received a Certification of Expected Separation under part 351 of this chapter or other official agency certification or notification indicating that the employee's position is surplus (for example, a notice of position abolishment or a notice of eligibility for discontinued service retirement).

(3) A current excepted service employee on a Schedule A or B appointment without time limit at grade level GS–15 (or equivalent) or below who is in an agency offering CTAP selection priority to its excepted service employees and who:

(i) Received a Certification of Expected Separation under part 351 of this chapter or other official agency certification indicating that the employee is surplus (for example, a notice of position abolishment, or notice of eligibility for discontinued service retirement); or

(ii) Received a RIF notice of separation under part 351 of this chapter or a notice of proposed removal under part 752 of this chapter for declining a directed geographic relocation outside the local commuting area (e.g., a directed reassignment or a change in duty station).

Vacancy means a vacant competitive service position at grade GS–15 (or equivalent) or below to be filled for a total of 121 days or more, including all extensions, regardless of whether the agency issues a specific vacancy announcement.

§ 330.603 Requirements for agency CTAPs.

(a) Each agency must establish a CTAP for their surplus and displaced employees. Each agency must send its plan, and any modifications, to OPM's Division of Strategic Human Resources Policy after approval by an authorized agency official.

(b) Each agency must uniformly and consistently apply its CTAP and these regulations to all surplus and displaced employees.

(c) In addition to a description of the agency's selection priority policies required by § 330.604, a CTAP must describe the agency's policies with regard to how it will provide career transition services to all its surplus and displaced agency employees, including excepted service and Senior Executive Service employees. The plan must describe:

(1) The types of career transition services the agency will provide;

(2) Policies on employees' and former employees' use of transition services and facilities, including:

(i) Excused absences for transition-related activities;

(ii) Access to services or facilities after separation;

(iii) Orientation sessions on career transition services and information as described in § 330.608(a) and (b), respectively;

(iv) Retraining policies;

(v) Access to agency CTAP services and resources by all employees, including those with disabilities, those in field offices, and those in remote sites;

(vi) Access to other Federal, State, and local resources available to support career transition for employees with disabilities; and

(vii) Availability of employee assistance programs and services.

(d) An agency's CTAP must also describe the agency's policies and procedures for its Reemployment Priority List established under subpart B of this part and the Interagency Career Transition Placement Plan established under subpart G of this part.

§ 330.604 Requirements for agency CTAP selection priority.

In addition to the overall requirements of § 330.603, an agency's CTAP must describe:

(a) How the agency will provide CTAP selection priority to surplus and displaced employees for vacancies in the local commuting area before selecting any other candidate from either within or outside the agency;

(b) Procedures for reviewing CTAP eligibles' qualifications and resolving qualification issues or disputes;

(c) Decisions involving discretionary areas under § 330.607 (such as whether excepted service employees will receive CTAP selection priority, priority of surplus versus displaced employees, designation of agency components, and selection priority beyond the local commuting area); and

(d) When and how the agency will inform its surplus and displaced employees about CTAP eligibility criteria, as required by § 330.608(b), how to apply for agency vacancies, and how to request CTAP selection priority.

§ 330.605 Agency responsibilities for well-qualified decisions.

(a) An agency must define what constitutes a well-qualified candidate for its specific vacancies, consistent with this subpart, and uniformly apply that definition to all CTAP eligibles being considered for the vacancy.

(b) An agency must conduct an independent second review and document the specific job-related reasons whenever a CTAP eligible is determined to be not well-qualified under the agency's definition. The agency must give the CTAP eligible the written results of this review as required by § 330.608(e).

§ 330.606 Minimum criteria for agency well-qualified definition.

(a) At a minimum, the agency must define ''well-qualified'' as having knowledge, skills, abilities, and/or competencies clearly exceeding the minimum qualification requirements for the vacancy. The agency definition may or may not equate to the highly or best qualified assessment criteria established for the vacancy; however, the agency definition of ''well-qualified'' must satisfy the criteria in paragraph (b) of this section.

(b) Under an agency's definition of ''well-qualified,'' the agency must be able to determine whether a CTAP eligible:

(1) Meets the basic eligibility requirements (including employment suitability requirements under part 731 of this chapter and any medical qualifications requirements), qualification standards (including minimum educational and experience requirements), and any applicable selective factors;

(2) Is physically qualified, with or without reasonable accommodation, to perform the essential duties of the position;

(3) Meets any special qualifying conditions of the position;

(4) Is able to satisfactorily perform the duties of the position upon entry; and

(5) At agency discretion, either:

(i) Rates at or above specified level(s) on all quality ranking factors; or

(ii) Rates above minimally qualified in the agency's rating and ranking process.

(c) An agency may include the results of a scored structured interview process in determining whether a CTAP eligible is well-qualified.

§ 330.607 Applying CTAP selection priority.

(a) An agency must not place any other candidate from within or outside

the agency into a vacancy if there is an available CTAP selection priority candidate, unless the personnel action to be effected is an exception under § 330.609.

(b) In accordance with the conditions of part 300, subpart E, of this chapter, an agency may not procure temporary help services under that subpart until a determination is made that no CTAP eligible is available.

(c) CTAP selection priority applies to a vacancy that:

(1) Is at a grade or pay level with a representative rate no higher than the representative rate of the grade or pay level of the CTAP eligible's permanent position of record;

(2) Has no greater promotion potential than the CTAP eligible's permanent position of record;

(3) Is in the same local commuting area as the CTAP eligible's permanent position of record;

(4) Is filled during the CTAP eligible's eligibility period; and, if applicable,

(5) Is filled under the same excepted appointing authority as the CTAP eligible's permanent position of record if the CTAP eligible is an excepted service employee and the agency CTAP provides selection priority in the excepted service.

(d) An agency may take actions under § 335.102 of this chapter to place a permanent competitive service employee into a vacancy if there are no CTAP eligible employees in the local commuting area or if no CTAP eligibles apply for the vacancy.

(e) An agency component may place a component employee within the local commuting area in the vacancy after the component applies CTAP selection priority to its employees.

(f) If there are two or more CTAP selection priority candidates for a vacancy, the agency may place any of them. An agency may decide the specific order of selection among CTAP selection priority candidates. For example, an agency may:

(1) Provide a displaced candidate higher priority than a surplus candidate; or

(2) Provide an internal component candidate higher priority than another component's candidate.

(g) After an agency makes the vacancy available to its CTAP eligibles and meets its obligation to any CTAP selection priority candidates, the agency may place into the vacancy any other permanent competitive service candidate from within its workforce, under appropriate staffing procedures.

(h) An agency may provide CTAP selection priority to eligible employees from another commuting area after fulfilling its obligation to CTAP selection priority candidates in the local commuting area.

(i) An agency may deny a CTAP eligible future selection priority if the eligible:

(1) Declines an offer of a permanent appointment at any grade or pay level in the competitive or excepted service; or

(2) Fails to respond within a reasonable period of time, as defined by the agency, to an offer of a permanent appointment at any grade or pay level in the competitive or excepted service.

(j) Before appointing an individual from outside the agency's permanent competitive service workforce, the agency must follow the requirements of subparts B and G of this part.

§ 330.608 Other agency CTAP responsibilities.

(a) An agency must make a career transition orientation session available to all agency surplus and displaced employees with information on selection priority under this subpart and subparts B and G. Such orientation sessions may be in person or web-based through an agency automated training system or intranet.

(b) An agency must give each agency CTAP eligible written information on selection priority under its plan, explaining how to locate and apply for agency vacancies and request selection priority. The agency may meet this requirement by providing a copy of its CTAP established under § 330.603.

(c) An agency must take reasonable steps to ensure that agency CTAP eligibles have access to information on all vacancies, including how CTAP eligibles can apply, what proof of eligibility is required, and the agency definition of ''well-qualified'' for the vacancy.

(d) If the agency can document that there are no CTAP eligibles in a local commuting area, the agency need not post the vacancy for CTAP eligibles.

(e) An agency must provide a CTAP eligible who applied for a specific vacancy written notice of the final status of his or her application, including whether the eligible was determined to be well-qualified. The agency notice must include the results of the independent, second review under § 330.605(b), if applicable; whether another CTAP selection priority candidate was hired; whether the position was filled under an exception listed in § 330.609; and whether the recruitment was cancelled.

§ 330.609 Exceptions to CTAP selection priority.

An agency may effect the following personnel actions as exceptions to § 330.607:

(a) Reemploy a former agency employee with regulatory or statutory reemployment rights, including the reemployment of an injured worker who either has been restored to earning capacity by the Office of Workers' Compensation Programs, Department of Labor, or has received a notice that his or her compensation benefits will cease because of full recovery from the disabling injury or illness;

(b) Reassign or demote an employee under part 432 or 752 of this chapter;

(c) Appoint an individual for a period limited to 120 or fewer days, including all extensions;

(d) Reassign agency employees between or among positions in the local commuting area (sometimes called job swaps) when there is no change in grade or promotion potential and no actual vacancy results;

(e) Convert an employee currently serving under an appointment providing noncompetitive conversion eligibility to a competitive service appointment, including from:

(1) A Veterans Recruitment Appointment under part 307 of this chapter;

(2) An appointment under 5 U.S.C. 3112 and part 316 of this chapter of a veteran with a compensable service-connected disability of 30 percent or more; and

(3) An excepted service appointment under part 213 of this chapter, such as for persons with disabilities or in the Presidential Management Fellow Program, the Student Career Experience Program, or the Federal Career Intern Program;

(f) A personnel action taken under, or specifically in lieu of, part 351 of this chapter;

(g) A position change of an employee into a different position as a result of a formal reorganization, as long as the former position ceases to exist and no actual vacancy results;

(h) Assign or exchange an employee under a statutory program, such as subchapter VI of chapter 33 of title 5, United States Code (also called the Intergovernmental Personnel Act), or the Information Technology Exchange Program under chapter 37 of title 5, United States Code;

(i) Appoint an individual under an excepted service appointing authority;

(j) A position change of an employee within the excepted service;

(k) Detail an employee within the agency;

(l) Promote an employee for a period limited to 120 or fewer days, including all extensions;

(m) A position change of a surplus or displaced employee in the local commuting area;

(n) A position change of an employee under 5 U.S.C. 8337 or 8451 to allow continued employment of an employee who is unable to provide useful and efficient service in his or her current position because of a medical condition;

(o) A position change of an employee to a position that constitutes a reasonable offer as defined in 5 U.S.C. 8336(d) and 8414(b);

(p) A position change of an employee resulting from a reclassification action (such as accretion of duties or an action resulting from application of new position classification standards);

(q) Promote an employee to the next higher grade or pay level of a designated career ladder position;

(r) Recall a seasonal or intermittent employee from nonpay status;

(s) A position change of an injured or disabled employee to a position in which he or she can be reasonably accommodated;

(t) A personnel action for an employee pursuant to the settlement of a formal complaint, grievance, appeal, or other litigation;

(u) Reassign or demote an employee under § 315.907 of this chapter for failure to complete a supervisory or managerial probationary period;

(v) Retain an individual whose position is brought into the competitive service under part 316 of this chapter and convert that individual, when applicable, under part 315 of this chapter;

(w) Retain an employee covered by an OPM-approved variation under Civil Service Rule 5.1 (5 CFR 5.1);

(x) Reemploy a former agency employee who retired under a formal trial retirement and reemployment program and who requests reemployment under the program's provisions and applicable time limits;

(y) Extend a time-limited promotion or appointment up to the maximum period allowed (including any OPM-approved extensions beyond the regulatory limit on the time-limited promotion or appointment), if the original action was made subject to CTAP selection priority and the original announcement or notice stated that the promotion or appointment could be extended without further announcement;

(z) Transfer an employee between agencies under appropriate authority during an interagency reorganization, interagency transfer of function, or interagency mass transfer;

(aa) Appoint a member from the Senior Executive Service into the competitive service under 5 U.S.C. 3594;

(bb) Transfer an employee voluntarily from one agency to another under a Memorandum of Understanding or similar agreement under appropriate authority resulting from an interagency reorganization, interagency transfer of function, or interagency mass transfer, when both the agencies and the affected employee agree to the transfer;

(cc) Reassign an employee whose position description or other written mobility agreement provides for reassignment outside the commuting area as part of a planned agency rotational program; or

(dd) Transfer or a position change of an employee under part 412 of this chapter.

§ 330.610 CTAP eligibility period.

(a) CTAP eligibility begins on the date the employee meets the definition of *surplus* or *displaced* in § 330.602.

(b) CTAP eligibility ends on the date that the employee:

(1) Separates from the agency either voluntarily or involuntarily;

(2) Receives a notice rescinding, canceling, or modifying the notice which established CTAP eligibility so that the employee no longer meets the definition of *surplus* or *displaced.*

(3) Is placed in another position within the agency at any grade or pay level, either permanent or time-limited, before the agency separates the employee; or

(4) Is appointed to a career, career-conditional, or excepted appointment without time limit in any agency at any grade or pay level.

§ 330.611 Establishing CTAP selection priority.

(a) CTAP selection priority for a specific agency vacancy begins when a CTAP eligible:

(1) Submits all required application materials, including proof of eligibility, within agency-established timeframes; and,

(2) The agency determines the eligible is well-qualified for the vacancy.

(b) An agency may allow CTAP eligible employees to become CTAP selection priority candidates for positions in other local commuting areas only if there are no CTAP selection priority candidates within the local commuting area of the vacancy.

(c) An agency may deny future CTAP selection priority for agency positions if the CTAP eligible declines an offer of permanent appointment at any grade level (whether it is a competitive or excepted appointment).

§ 330.612 Proof of eligibility.

(a) The CTAP eligible must submit a copy of one of the documents listed under the definition of *displaced* or *surplus* in § 330.602 to establish selection priority under § 330.611.

(b) The CTAP eligible may also submit a copy of a RIF notice with an offer of another position, accompanied by the signed declination of the offer. The RIF notice must state that declination of the offer will result in separation under RIF procedures.

§ 330.613 OPM's role in CTAP.

OPM has oversight of CTAP and may conduct reviews of agency compliance and require corrective action at any time.

Subpart G—Interagency Career Transition Assistance Plan (ICTAP) for Displaced Employees

§ 330.701 Purpose.

The Interagency Career Transition Assistance Program (ICTAP) provides eligible displaced Federal employees with interagency selection priority for vacancies in agencies that are filling positions from outside their respective permanent competitive service workforces. The ICTAP selection priority does not apply in the ICTAP eligible's current or former agency and it does not prohibit movement of permanent competitive service employees within an agency, as permitted by subpart F of this part. This subpart establishes requirements for ICTAP selection priority.

§ 330.702 Definitions.

In this subpart:

Displaced means an individual in one of the following categories:

(1) A current career or career-conditional (tenure group I or II) competitive service employee of any agency at grade GS–15 (or equivalent) or below whose current performance rating of record is at least fully successful (Level 3) or equivalent and who:

(i) Received a reduction in force (RIF) separation notice under part 351 of this chapter and has not declined an offer under part 351, subpart G, of this chapter of a position with the same type of work schedule and a representative rate at least as high as that of the position from which the employee will be separated; or

(ii) Received a notice of proposed removal under part 752 of this chapter for declining a directed geographic relocation outside the local commuting

area (e.g., a directed reassignment or a change in duty station).

(2) A former career or career-conditional (tenure group I or II) competitive service employee of any agency at grade GS–15 (or equivalent) or below whose last performance rating of record was at least fully successful (Level 3) or equivalent who was either:

(i) Separated by RIF under part 351 of this chapter and did not decline an offer under part 351, subpart G, of this chapter of a position with the same type of work schedule and a representative rate at least as high as that of the position from which the employee was separated; or

(ii) Removed under part 752 of this chapter for declining a directed geographic relocation outside the local commuting area (e.g., a directed reassignment or a change in duty station).

(3) A former career or career-conditional employee of any agency who was separated because of a compensable work-related injury or illness as provided under 5 U.S.C. chapter 81, subchapter I, whose compensation was terminated and who has received certification from the former employing agency that it is unable to place the employee as required by part 353 of this chapter.

(4) A former career or career-conditional (tenure group I or II) competitive service employee of any agency who retired with a disability annuity under 5 U.S.C. 8337 or 8451 and who has received notification from OPM that the disability annuity has been or will be terminated.

(5) A former Military Reserve Technician or National Guard Technician receiving a special disability retirement annuity under 5 U.S.C. 8337(h) or 8456 and who has certification of such annuity from the military department or National Guard Bureau.

(6) A current or former excepted service employee on an appointment without time limit at grade GS–15 (or equivalent) or below whose current or last performance rating of record is or was at least fully successful (Level 3) or equivalent and who:

(i) Has been provided by law with both noncompetitive appointment eligibility and selection priority for competitive service positions; and

(ii) Has received a RIF separation notice under part 351 of this chapter or notice of proposed removal under part 752 of this chapter for declining a directed geographic relocation outside the local commuting area (*e.g.,* a directed reassignment or a change in duty station) or has been separated by RIF procedures or removed for declining a geographic relocation outside the local commuting area.

ICTAP eligible means an individual who meets the definition of *displaced.* As used in this subpart, ''ICTAP eligible'' and ''eligible'' are synonymous.

ICTAP selection priority candidate means an ICTAP eligible who applied for a vacancy, was determined by the agency to be well-qualified for that vacancy, and who the agency must select over any other candidate from outside the agency's current competitive service workforce for the vacancy, unless the action to be taken is listed as an exception under § 330.707.

Vacancy means a vacant competitive service position at grade GS–15 (or equivalent) or below to be filled for 121 days or more, including extensions.

§ 330.703 Agency responsibilities for well-qualified decisions.

(a) Agencies must define ''well-qualified'' for their specific vacancies, consistent with this subpart, and uniformly apply that definition to all ICTAP eligibles being considered for the vacancy.

(b) Agencies must conduct an independent second review and document the specific job-related reasons whenever an ICTAP eligible is determined to be not well-qualified for the vacancy under the agency's definition. An agency must give the ICTAP eligible the written results of this review as required by § 330.706(d).

§ 330.704 Minimum criteria for agency well-qualified definition.

(a) At a minimum, agencies must define ''well-qualified'' as having knowledge, skills, abilities, and/or competencies clearly exceeding the minimum qualification requirements for the vacancy. The agency definition may or may not equate to the highly or best qualified assessment criteria established for the vacancy; however, the agency definition of ''well-qualified'' must satisfy the criteria in paragraph (b) of this section.

(b) Under an agency's definition of ''well-qualified,'' the agency must be able to determine whether an ICTAP eligible:

(1) Meets the basic eligibility requirements (including employment suitability requirements under part 731 of this chapter and any medical qualification requirements), qualification standards (including minimum educational and experience requirements), and any applicable selective factors;

(2) Is physically qualified, with or without reasonable accommodation, to perform the essential duties of the position;

(3) Meets any special qualifying conditions of the position;

(4) Is able to satisfactorily perform the duties of the position upon entry; and

(5) At agency discretion, either:

(i) Rates at or above specified level(s) on all quality ranking factors; or

(ii) Rates above minimally qualified in the agency's rating and ranking process.

(c) An agency may include the results of a scored structured interview process in determining whether an ICTAP eligible is well-qualified.

§ 330.705 Applying ICTAP selection priority.

(a) An agency must not appoint any candidate from outside its permanent competitive service workforce if there is an ICTAP selection priority candidate available for the vacancy, unless the personnel action to be effected is an exception under § 330.707.

(b) ICTAP selection priority applies to a vacancy that:

(1) Is at a grade or pay level with a representative rate no higher than the representative rate of the grade or pay level of the ICTAP eligible's current or last permanent position of record;

(2) Has no greater promotion potential than the ICTAP eligible's current or last permanent position of record;

(3) Is in the same local commuting area as the ICTAP eligible's current or last permanent position of record; and

(4) Is filled during the ICTAP eligible's eligibility period.

(c) An agency may appoint any ICTAP selection priority candidate for a vacancy.

(d)(1) After an agency announces the vacancy and meets its obligation to any ICTAP selection priority candidates, the agency may appoint any other candidate from outside its current permanent competitive service workforce, under appropriate staffing procedures.

(2) An agency may make additional selections or reissue selection certificates in accordance with its merit promotion program without readvertising for ICTAP eligibles only if the additional selections are made from the applicant pool established by the original vacancy announcement, including readvertisements for the same vacancy.

(e) An agency may deny an ICTAP eligible future selection priority for vacancies in that agency if the ICTAP eligible:

(1) Declines an offer of a permanent appointment at any grade or pay level in the competitive or excepted service; or

(2) Fails to respond within a reasonable period of time, as defined by

the agency, to an offer or official inquiry of availability for a permanent appointment at any grade or pay level in the competitive or excepted service.

(f) An agency may deny an ICTAP eligible future selection priority for a position previously obtained through ICTAP if the eligible was terminated or removed from that position under part 432 or 752 of this chapter.

§ 330.706 Other agency ICTAP responsibilities.

(a) Before appointing any other candidate from outside the agency's permanent competitive service workforce, the agency must first fulfill its obligation to any employees entitled to selection priority under subparts B and F of this part.

(b) In accordance with the conditions of part 300, subpart E, of this chapter, an agency may not procure temporary help services under that subpart until a determination is made that no ICTAP eligible is available.

(c) An agency must announce all vacancies it intends to fill from outside its permanent competitive service workforce. Vacancy announcements must meet the requirements of subpart A of this part.

(d) An agency must provide an ICTAP eligible who applied for a specific vacancy written notice of the final status of his or her application, including whether the eligible was determined to be well-qualified. The agency notice must include the results of the independent second review under § 330.703(b), if applicable; whether another ICTAP selection priority candidate was hired; whether the position was filled under an exception listed in § 330.707; and whether the recruitment was cancelled.

§ 330.707 Exceptions to ICTAP selection priority.

An agency may effect the following personnel actions as exceptions to § 330.705:

(a) Place a current or reinstate a former agency employee with RPL selection priority under subpart B of this part;

(b) A position change of a current permanent competitive service agency employee;

(c) Appoint a 10-point veteran preference eligible through an appropriate appointing authority;

(d) Reemploy a former agency employee with regulatory or statutory reemployment rights, including the reemployment of an injured worker who either has been restored to earning capacity by the Office of Workers' Compensation Programs, Department of Labor, or has received a notice that his or her compensation benefits will cease because of recovery from disabling injury or illness;

(e) Appoint an individual for a period limited to 120 or fewer days, including all extensions;

(f) A personnel action effected under, or specifically in lieu of, part 351 of this chapter;

(g) Appoint an individual under an excepted service appointing authority;

(h) Convert an employee serving under an appointment that provides noncompetitive conversion eligibility to a competitive service appointment, including from:

(1) A Veterans Recruitment Appointment under part 307 of this chapter;

(2) An appointment under 5 U.S.C. 3112 and part 316 of this chapter of a veteran with a compensable service-connected disability of 30 percent or more;

(3) An excepted service appointment under part 213 of this chapter, such as for persons with disabilities or in the Presidential Management Fellow Program, the Student Career Experience Program, or the Federal Career Intern Program;

(i) Transfer an employee between agencies under appropriate authority during an interagency reorganization, interagency transfer of function, or interagency mass transfer;

(j) Reemploy a former agency employee who retired under a formal trial retirement and reemployment program and who requests reemployment under the program's provisions and applicable time limits;

(k) A personnel action for an employee pursuant to the settlement of a formal complaint, grievance, appeal, or other litigation;

(l) Extend a time-limited appointment up to the maximum period allowed (including any OPM-approved extension past the regulatory limit on the time-limited appointment), if the original action was made subject to ICTAP selection priority and the original vacancy announcement stated that the appointment could be extended without further announcement;

(m) Reappoint a former agency employee into a hard-to-fill position requiring unique skills and experience to conduct a formal skills-based agency training program;

(n) Retain an individual whose position is brought into the competitive service under part 316 of this chapter and convert that individual, when applicable, under part 315 of this chapter;

(o) Retain an employee covered by an OPM-approved variation under Civil Service Rule 5.1 (5 CFR 5.1);

(p) Appoint a member from the Senior Executive Service into the competitive service under 5 U.S.C. 3594;

(q) Assign or exchange an employee under a statutory program, such as subchapter VI of chapter 33 of title 5, United States Code (also called the Intergovernmental Personnel Act), or the Information Technology Exchange Program under chapter 37 of title 5, United States Code;

(r) Detail an employee to another agency;

(s) Transfer employees under an OPM-approved interagency job swap plan designed to facilitate the exchange of employees between agencies to avoid or minimize involuntary separations;

(t) Transfer or reinstate an ICTAP eligible who meets the agency's definition of ''well-qualified'';

(u) Transfer an employee voluntarily from one agency to another under a Memorandum of Understanding or similar agreement under appropriate authority resulting from an interagency reorganization, interagency transfer of function, or interagency realignment, when both the agencies and the affected employee agree to the transfer; or

(v) Transfer or a position change of an employee under part 412 of this chapter.

§ 330.708 ICTAP eligibility period.

(a) ICTAP eligibility begins on the date the employee or former employee meets the definition of *displaced* in § 330.702.

(b) ICTAP eligibility ends 1 year from the date of:

(1) Separation by RIF under part 351 of this chapter;

(2) Removal by the agency under part 752 of this chapter for declining a directed geographic relocation outside the local commuting area (*e.g.,* a directed reassignment or a change in duty station);

(3) Agency certification that it cannot place the employee under part 353 of this chapter; or

(4) OPM notification that an employee's disability annuity has been, or will be, terminated.

(c) ICTAP eligibility ends 2 years after RIF separation if eligible under subpart D of this part.

(d) ICTAP eligibility also ends on the date the eligible:

(1) Receives a notice rescinding, canceling, or modifying the notice which established ICTAP eligibility so that the employee no longer meets the definition of *displaced* in § 330.702;

(2) Separates from the agency for any reason before the RIF or removal effective date; or

(3) Is appointed to a career, career-conditional, or excepted appointment without time limit in any agency at any grade or pay level.

(e) OPM may extend the eligibility period when an ICTAP eligible does not receive a full 1 year (or 2 years under subpart D of this part) of eligibility, for example, because of administrative or procedural error.

§ 330.709 Establishing ICTAP selection priority.

ICTAP selection priority for a specific vacancy begins when an ICTAP eligible:

(a) Submits all required application materials, including proof of eligibility, within agency-established timeframes; and

(b) The agency determines the eligible is well-qualified for the vacancy.

§ 330.710 Proof of eligibility.

(a) The ICTAP eligible must submit a copy of one of the documents listed under the definition of *displaced* in § 330.702 to establish selection priority under § 330.709.

(b) The ICTAP eligible may also submit a copy of the RIF notice with an offer of another position accompanied by the signed declination of that offer. The RIF notice must state that declination of the offer will result in separation under RIF procedures.

§ 330.711 OPM's role in ICTAP.

OPM has oversight of ICTAP and may conduct reviews of agency compliance and require corrective action at any time.

Subparts H–I—[Reserved]

Subpart J—Prohibited Practices

§ 330.1001 Withdrawal from competition.

An applicant for competitive examination, an eligible on a register, and an officer or employee in the Executive branch of the Government may not persuade, induce, or coerce, or attempt to persuade, induce, or coerce, directly or indirectly, a prospective applicant to withhold filing an application, or an applicant or eligible to withdraw from competition or eligibility, for a position in the competitive service, for the purpose of improving or injuring the prospects of an applicant or eligible for appointment. OPM will cancel the application or eligibility of an applicant or eligible who violates this section, and will impose such other penalty as it considers appropriate.

Subpart K–L—[Reserved]

PART 335—PROMOTION AND INTERNAL PLACEMENT

4. The authority citation for part 335 continues to read as follows:

Authority: 5 U.S.C. 3301, 3302, 3330; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; 5 U.S.C. 3304(f), and Pub. L. 106–117.

§ 335.105 [Amended]

5. In § 335.105, remove the phrase ''§ 330.707 of subpart G'' and add in its place the phrase, ''part 330, subpart A''.

PART 337—EXAMINING SYSTEM

6. The authority citation for part 337 continues to read as follows:

Authority: 5 U.S.C. 1104(a), 1302, 2302, 3301, 3302, 3304, 3319, 5364; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; 33 FR 12423, Sept. 4, 1968; and 45 FR 18365, Mar. 21, 1980; 116 Stat. 2135, 2290; and 117 Stat 1392, 1665.

§ 337.203 [Amended]

7. In § 337.203, remove the phrase ''subpart G'' and add in its place the phrase, ''subpart A''.

PART 410—TRAINING

8. The authority citation for part 410 continues to read as follows:

Authority: 5 U.S.C. 4101, *et seq.*; E.O. 11348, 3 CFR, 1967 Comp., p. 275.

§ 410.307 [Amended]

9. In § 410.307:

a. In paragraph (c)(3), remove the phrase ''5 CFR 330.604(b) and (f)'' and add in its place the phrase, ''5 CFR 330.602''.

b. In paragraph (c)(4), remove the phrase ''5 CFR 330.602'' and add in its place the phrase, ''5 CFR part 330, subpart F''.

[FR Doc. E8–20657 Filed 9–5–08; 8:45 am]

BILLING CODE 6325–39–P

FEDERAL ELECTION COMMISSION

11 CFR Parts 100 and 104

[Notice 2008–09]

Reporting Contributions Bundled by Lobbyists, Registrants and the PACs of Lobbyists and Registrants

AGENCY: Federal Election Commission.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: The Federal Election Commission is announcing a public hearing on the proposed rules governing the disclosure of information about bundled contributions provided by certain lobbyists, registrants and their PACs.

DATES: The hearing will be held on Wednesday, September 17, 2008 and will begin at 9:30 a.m.

ADDRESSES: Commission hearings are held in the Commission's ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Amy L. Rothstein, Assistant General Counsel, or Ms. Cheryl A.F. Hemsley, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: On November 6, 2007, the Commission published a Notice of Proposed Rulemaking (''NPRM'') proposing rules governing the disclosure of information about bundled contributions provided by certain lobbyists, registrants and their PACs. *Reporting Contributions Bundled by Lobbyists, Registrants and the PACs of Lobbyists and Registrants*, 72 FR 62,600 (Nov. 6, 2007). The deadline for comments on the NPRM was Nov. 30, 2007. In the NPRM, the Commission stated that it would announce the date of a hearing at a later date.

Accordingly, the hearing will be held on Wednesday, September 17, 2008 (see **DATES** and **ADDRESSES**, above). Witnesses will be limited to those individuals who indicated in their timely comments on the NPRM that they wished to testify at the hearing. Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mary Dove, Commission Secretary, at (202) 694–1040, at least 72 hours prior to the hearing date.

Dated: September 2, 2008.

On behalf of the Commission.

Ellen Weintraub,

Commissioner, Federal Election Commission.

[FR Doc. E8–20810 Filed 9–5–08; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0908; Directorate Identifier 2007–NM–190–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series Airplanes

Correction

In proposed rule document E8–19715 beginning on page 50250 in the issue of Tuesday, August 26, 2008, make the following correction:

§39.13 [Corrected]

On page 50253, in §39.13, Table 1 should read as set forth below:

TABLE 1—REVISED REPETITIVE INTERVALS FOR CERTAIN DETAILED INSPECTIONS

For model—	Repeat the inspection at the later of the following times—		And thereafter at intervals not to exceed—
(1) A310–200 series airplanes	Within 950 flight cycles or 1,900 flight hours since the last inspection required by paragraph (f)(1)(i) or (i) of this AD, whichever occurs first.	Within 50 flight cycles or 250 flight hours after the effective date of this AD, whichever occurs first.	950 flight cycles or 1,900 flight hours, whichever occurs first.
(2) A310–300 series airplanes (short range)	Within 900 flight cycles or 2,550 flight hours since the last inspection required by paragraph (f)(1)(ii) or (i) of this AD, whichever occurs first.	Within 50 flight cycles or 250 flight hours after the effective date of this AD, whichever occurs first.	900 flight cycles or 2,550 flight hours, whichever occurs first.
(3) A310–300 series airplanes (long range)	Within 800 flight cycles or 4,000 flight hours since the last inspection required by paragraph (f)(1)(ii) or (i) of this AD, whichever occurs first.	Within 50 flight cycles or 250 flight hours after the effective date of this AD, whichever occurs first.	800 flight cycles or 4,000 flight hours, whichever occurs first.

[FR Doc. Z8–19715 Filed 9–5–08; 8:45 am]
BILLING CODE 1505–01–D

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 40, 41 and 145

RIN 3038–AC44

Confidential Information and Commission Records and Information

AGENCY: Commodity Futures Trading Commission.

ACTION: Extension of comment period.

SUMMARY: On August 1, 2008, the Commission published in the **Federal Register** a notice of proposed rulemaking to amend the procedures under which designated contract markets, derivatives clearing organizations and derivatives transaction execution facilities (collectively, ''registered entities'') may request confidential treatment for products and rules submitted via certification procedures or for Commission review and approval pursuant to parts 40 and 41 of the Commission's regulations.[1] Comments on the proposal originally were due on September 2, 2008. The Commission is extending the comment period in order to give interested persons additional time to comment on the proposed amendments.

DATES: Comments must be received by September 17, 2008.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail/Hand Deliver:* David Stawick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *E-mail: secretary@cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Nathan, Senior Special Counsel, (202) 418–5133; Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. E-mail: *snathan@cftc.gov.*

SUPPLEMENTARY INFORMATION: On August 1, 2008, the Commission published and sought public comment on proposed amendments to part 40 of the Commission's regulations to establish the exclusive procedure to be followed by registered entities when requesting confidential treatment for information required to be filed under parts 40 and 41, and to clarify the circumstances under which requests for confidential treatment will not be considered. Most confidential treatment requests are made pursuant to Commission regulation 145, 17 CFR 145, which implements the Freedom of Information Act, 5 U.S.C. 552 (FOIA). The FOIA provides generally that the public has a right of access to agency records except to the extent that the records, or portions of them, are protected from disclosure by one or more of nine exemptions.

A registered entity requesting confidential treatment typically invokes FOIA exemption (b)(4) on the ground that release of its information will cause it commercial or competitive harm. Although registered entities are required to make public much of the information required by parts 40 and 41 of the Commission's regulations, registered entities frequently request confidential treatment for filings submitted under these parts. The confidential treatment procedures established by Commission regulation 145.9 provide that requests for confidentiality are not considered on the merits unless and until a FOIA request is received for the specific

[1] 73 FR 44939 (Aug. 1, 2008).

material. Accordingly, the Commission frequently is unable to act on requests for confidential treatment of information it believes should be made publicly available. The proposed amendments are intended to permit staff to promptly resolve confidentiality issues in connection with material submitted pursuant to parts 40 and 41 by creating, as permitted by part 145, a separate procedure from that specified in regulation 145.9. The proposed procedure would not be triggered by a FOIA request but instead would require that registered entities desiring confidential treatment for information submitted under parts 40 and 41 simultaneously file a detailed written justification in support of such a request. Commission staff would make an initial determination to grant or deny confidential treatment. The proposed amendments to part 40 provide a process under which a registered entity may appeal the staff's decision and further provide that in the event of a subsequent FOIA request, both the requester and the submitter would have the appeal rights specified in Commission regulation 145.9.

The comment period closes on September 2, 2008. By letter dated August 29, 2008, The Chicago Mercantile Exchange requested additional time to address the issues raised in the proposed rulemaking. In order to encourage the submission of meaningful comments and to assure that all views are considered in its final determination, the Commission has determined to grant the request and to give full consideration to any comment received during the extension period. Accordingly, the comment period for the Commission's proposed amendments to parts 40, 41 and 145 is hereby extended to September 17, 2008.

Issued in Washington, DC on September 2, 2008, by the Commission.

Sauntia S. Warfield,

Staff Assistant.

[FR Doc. E8–20684 Filed 9–5–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 4, 7, 10, 102, 134, and 177

[USCBP–2007–0100]

RIN 1505–AB49

Uniform Rules of Origin for Imported Merchandise

AGENCIES: Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: This document provides an additional 30 days for interested parties to submit comments on the proposed rule to amend the Customs and Border Protection (''CBP'') regulations to establish uniform rules governing CBP determinations of the country of origin of imported merchandise. The proposed rule was published in the **Federal Register** on July 25, 2008 (73 FR 43385), and the comment period was scheduled to expire on September 23, 2008.

DATES: Comments on the proposed rule must be received on or before October 23, 2008.

ADDRESSES: You may submit comments, identified by docket number, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments via docket number USCBP–2007–0100.
- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., (Mint Annex), Washington, DC 20229.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572–8768.

FOR FURTHER INFORMATION CONTACT: Monika Brenner, Valuation and Special Programs, Office of International Trade, 202–572–8835; Heather K. Pinnock, Tariff Classification and Marking, Office of International Trade, 202–572–8828.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to CBP will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. See **ADDRESSES** above for information on how to submit comments.

Background

CBP published a notice of proposed rulemaking in the **Federal Register** (73 FR 43385) on July 25, 2008, proposing to amend the CBP regulations to establish uniform rules of origin for imported merchandise. The proposed rule would extend application of the country of origin rules codified in 19 CFR part 102. Those rules have proven to be more objective and transparent and provide greater predictability in determining the country of origin of imported merchandise than the system of case-by-case adjudication they would replace. The proposed change also will aid an importer's exercise of reasonable care. In addition, the document proposes to amend the country of origin rules applicable to pipe fitting and flanges, printed greeting cards, glass optical fiber, and rice preparations. Finally, the proposed rule would amend the textile regulations set forth in § 102.21 to make corrections so that the regulations reflect the language of section 334(b)(5) of the Uruguay Round Agreements Act.

The notice of proposed rulemaking invited the public to comment on the proposal. Comments on the proposed

rule were requested on or before September 23, 2008.

Extension of Comment Period

In response to the proposed rule published in the **Federal Register**, CBP has received correspondence from several parties requesting an extension of the comment period. A decision has been made to grant an extension of 30 days. Comments are now due on or before October 23, 2008.

Dated: September 2, 2008.

Harold M. Singer,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of International Trade.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade and Tariff Policy), Office of Tax Policy, United States Treasury Department.

[FR Doc. E8–20662 Filed 9–5–08; 8:45 am]

BILLING CODE 9111–14–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 408, 416, and 422

[Docket No. SSA–2007–0068]

RIN 0960–AG56

Revisions to Rules on Representation of Parties

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We are proposing several revisions to our rules on representation of parties. These proposed rules would recognize entities as representatives, define the concept of a principal representative, and authorize principal representatives to sign and file a claim for benefits on behalf of a claimant. These proposed rules would also mandate the use of Form SSA–1696 to appoint, revoke, or withdraw an appointment of a representative, and to waive a fee or direct payment of the fee. We propose to define the concept of a professional representative and require professional representatives to use our electronic services as they become available, including requiring professional representatives to submit certain requests for reconsideration or a hearing before an administrative law judge (ALJ) electronically. Finally, we propose to require representatives to keep paper copies of certain documents that we may require. We are proposing these revisions to reflect changes in representatives' business practices and to improve our efficiency by enhancing use of the Internet.

DATES: To make sure that your comments are considered, we must receive them no later than November 7, 2008.

ADDRESSES: You may submit comments by any one of four methods—Internet, facsimile, regular mail, or hand-delivery. Commenters should not submit the same comments multiple times or by more than one method. Regardless of which of the following methods you choose, please state that your comments refer to Docket No. SSA–2007–0068 to ensure that we can associate your comments with the correct regulation:

1. Federal eRulemaking portal at *http://www.regulations.gov.* (This is the most expedient method for submitting your comments, and we strongly urge you to use it.) In the *Search Documents* section of the Web page, type ''SSA–2007–0068'', select ''Go'', and then click ''Send a Comment or Submission.'' The Federal eRulemaking portal issues you a tracking number when you submit a comment.
2. Telefax to (410) 966–2830.
3. Letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, MD 21235–7703.
4. Deliver your comments to the Office of Regulations, Social Security Administration, 922 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between 8 a.m. and 4:30 p.m. on regular business days.

All comments are posted on the Federal eRulemaking portal, although they may not appear for several days after receipt of the comment. You may also inspect the comments on regular business days by making arrangements with the contact person shown in this preamble.

Caution: All comments we receive from members of the public are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov.* Therefore, you should be careful to include in your comments only information that you wish to make publicly available on the Internet. We strongly urge you not to include any personal information, such as your Social Security number or medical information, in your comments.

FOR FURTHER INFORMATION CONTACT: Marg Handel, Supervisory Social Insurance Specialist, Office of Income Security Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–4639. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html.*

Explanation of Changes

Background

We may issue rules and regulations to administer the provisions of the Act. 42 U.S.C. 405(a), 902(a)(5), 810(a), and 1383(d)(1). Specifically, we may issue regulations to recognize agents or other persons, other than attorneys, as representatives of individuals claiming benefits under the programs we administer. 42 U.S.C. 406(a)(1) and 1383(d)(2). We may also issue regulations to administer the Special Benefits for Certain World War II Veterans program, 42 U.S.C. 1010, and we have extended the rules by which we appoint and discipline representatives for claims under that program except where to do so would be impractical or contrary to the Act. 20 CFR 408.1101. Pursuant to the cited authority, we propose to revise our current regulations on Representation of Parties found in part 404 subparts G, J, and R, part 408 subpart K, part 416 subparts C, N, and O, and part 422 subparts C and F.

Recognizing Entities as Representatives

Individuals who want to obtain benefits from us may want someone to help them through the application process. Frequently, such claimants formally appoint a representative to act on their behalf and help guide their claim. A representative may, on behalf of a claimant, obtain and submit information and evidence about the claim, make statements about facts and law, and make requests or give notices about the claim to us. In return, the representative may receive a fee for their services from a portion of the claimant's past-due benefits.

Currently, we recognize attorneys or other ''persons'' as representatives of individuals who claim benefits under title II or title XVI of the Act. 42 U.S.C. 406(a)(1) and 1383(d)(1). Although the term ''person'' is defined broadly in the Act to include partnerships, corporations, and associations, we have previously chosen to recognize only individuals as representatives of claimants. In the decades since we adopted that policy, the business practices of those who represent claimants have changed significantly. Many representatives now practice in group settings and provide their services collectively to claimants. In addition, many claimants may prefer to hire a

firm rather than a single individual within the firm. Recognizing entities as representatives will make it easier for individuals to obtain the representation they want. We believe it is appropriate for us to propose to amend our rules to more accurately reflect the changes in the way representatives conduct their businesses.

Under our current process, we require the filing of a new Form SSA–1696, Appointment of Representative, to appoint each individual associated with an entity who represents a claimant before us. By recognizing entities as representatives, we will give claimants better flexibility to pursue their claims by not requiring the filing of a new Form SSA–1696 for each entity employee who represents a claimant during the claims process. This proposal will allow entities who represent claimants to alternate employees to represent a claimant based on availability and workload. However, an entity will be bound by the signatures and actions of its employees during their association with the entity, regardless of whether that association ends at a later date. If the claimant appoints an entity as his or her representative, the entity employee who signs the Form SSA–1696 on behalf of the entity will be considered the contact person for the entity for the purpose of receiving notices and information from us until or unless the entity updates its contact person information.

The proposed change also will allow us to properly pay entities for the representational services they provide to claimants, if certain conditions are met. It also makes our reporting to the Internal Revenue Service (IRS) and the issuance of Form IRS 1099-MISC to entities more efficient. We propose to permit ''direct payment'' of fees to entities if the employees who perform representational services on their behalf meet our requirements for direct payment. 42 U.S.C. 406 and the Social Security Protection Act of 2004 (SSPA), Public Law 108–203, section 301.

We propose to include these rules in §§ 404.1703, 404.1710, 404.1712, 404.1715, 404.1720, 404.1730, 404.1732, 416.1503, 416.1510, 416.1512, 416.1515, 416.1520, 416.1530, and 416.1732. We also propose to make conforming changes to other sections.

Multiple Representatives and the Role of a Principal Representative

We propose new rules explaining our current policy that a claimant may appoint multiple representatives to represent him or her at the same time. A claimant may appoint one or more individuals or entities to work on his or her claim at the same time. A principal representative is responsible for disseminating information and requests from us to a claimant and the claimant's other representatives, if any. It is our current practice to require a claimant to appoint a principal representative only if the claimant appoints more than one representative. We now propose to require that a claimant choose and appoint a principal representative. If a claimant appoints only one representative, that individual or entity is the principal representative.

If a principal representative's authority ends for any reason, and the claimant continues to be represented by only one appointed representative, we will consider that appointed representative to be the claimant's principal representative until the claimant files a new Form SSA–1696 with us designating another principal representative. If a principal representative's authority ends for any reason, and the claimant continues to be represented by multiple representatives, we will name one of the appointed representatives as the principal representative. The claimant may change the principal representative by filing a new Form SSA–1696.

We also propose to allow principal representatives to sign and file applications on behalf of claimants, provided the claimant has opportunity to review and verify the accuracy of the completed application. We expect this change to expedite the claims filing process, simplify the application process for some claimants, and afford the principal representative the opportunity to better serve the client. However, a claimant will have to expressly acknowledge on the Form SSA–1696 that he or she is responsible for the information provided to the principal representative for the application. We believe that this type of acknowledgement is necessary to ensure that the claimant remains responsible for the content of the application.

We will send to a claimant and his or her representatives notices relating to the appointment of a principal representative and other representatives, the revocation of the appointment of any representative, and the withdrawal of any representative. We will also send notices regarding the release of a claimant's past-due benefits to any representative who fails to file a request for approval of a fee.

Through these changes, we believe that we will better accommodate the needs of claimants and their representatives, that claimants' representatives will be better able to serve their clients, and that we will process fee payments more efficiently.

We propose to include these rules in §§ 404.612, 404.1700, 404.1703, 404.1705, 404.1707, 404.1710, 404.1715, 408.1101, 416.315, 416.1500, 416.1503, 416.1505, 416.1507, 416.1510, and 416.1515.

The Role of a Professional Representative

We propose to introduce the concept of a professional representative and to distinguish it from a principal representative. A professional representative includes any attorney, any individual other than an attorney, or any entity that holds itself out to the public as providing representational services before us (see §§ 404.1735 and 416.1535), regardless of whether the representative charges or collects a fee for providing the representational services.

We also propose to require that professional representatives conduct business with us electronically at the times and in the manner that we prescribe. For example, we intend to require a professional representative to use electronic media that we prescribe, such as the Internet, to register with us and to file certain requests for reconsideration and hearings before an ALJ. We are continuing to improve access for claimants, representatives, and the general public to forms and information about our programs by automating more of our business processes. When we have completed the automation of a specific business process that we intend to require, such as the use of Form SSA–1696, Appointment of Representative, we will announce in the **Federal Register** that the process has been automated and will be required.

If a professional representative cannot access our system because the representative's system is not functioning, our system is not functioning, the electronic media is not available, or because the representative's system cannot communicate with our system, we will waive the requirement that the professional representative use the electronic media that we prescribe. If the error is related to the representative's system rather than our system, we will require some type of documentation explaining why the representative is requesting the waiver.

We are particularly interested in receiving public comment on our definition of ''professional representative.'' While we believe that the proposed definition covers the vast majority of representatives who do

business with us, we are interested in receiving public comment on whether our proposed definition adequately includes all relevant organizations.

We propose to include these rules in §§ 404.910, 404.934, 404.1703, 404.1707, 404.1713, 416.1410, 416.1434, 416.1503, 416.1507, and 416.1513.

Access Registration

We propose to require professional representatives and their employees to complete an initial access registration with us through the use of electronic media that we prescribe. Representatives who are not classified as professional representatives and their employees will also be required to complete an initial access registration with us, but will be permitted to do so either electronically or by other means. Access registration requires representatives and their employees to supply us with certain personal, professional, and business affiliation information that we will use to authenticate and authorize representatives and their employees to do business with us. This initial registration will also require professional representatives and their employees to provide us with specific attestations to ensure that they know, understand, and will comply with our rules and regulations. Access registration is a one-time process, and it will allow us to process each claim more efficiently. However, representatives and their employees must update the access registration if their personal, professional, or business affiliation information changes. The authorization and authentication process will also assist us in safeguarding the personally identifiable information provided to us.

We propose to include these rules in §§ 404.1703, 404.1705, 404.1713, 416.1503, 416.1505, and 416.1513.

Direct Payment Registration

We pay representatives' fees out of a portion of the past-due benefits for claims under title II of the Act. Under provisions of the SSPA, we also are authorized to withhold and pay fees approved for attorneys in title XVI cases, and to withhold and pay fees approved for certain non-attorney representatives in cases under title II and title XVI of the Act.

On October 2, 2006, we published a notice in the **Federal Register** that advised both attorneys and eligible non-attorney representatives of additional requirements that a representative must meet in order for us to pay some or all of an approved fee directly to the representative from a claimant's past-due benefits. 71 FR 58043. That notice explained the registration process that a representative must complete in order to receive direct fee payment in a specific claim. We now propose to pay all representative fees via electronic funds transfer. This proposal will allow us to make direct payment of the representative's fee more efficiently, to more accurately report payments to the IRS, and to issue IRS Form 1099–MISC more quickly.

To ensure that we only make direct payments for work done by attorneys and eligible non-attorneys, there are certain actions that must be taken before an entity may receive direct payment of fees. Any entity seeking direct payment of fees must maintain, and provide to us upon our request, a signed statement from each of the entity's attorneys and eligible non-attorneys who represent claimants before us. The statement must state that the attorney or eligible non-attorney is performing representational services on behalf of the entity. The statement must also assert that any fees should be paid directly to the entity and that the representatives receive any compensation directly from the entity. Any request for direct payment of fees made by an entity must include an attestation that the entity is in possession of this signed statement from each attorney or eligible non-attorney who has performed any representational services for the claim in question. Additionally, the entity must attest that all individuals who have performed representational services on the claim in question are individuals who qualify for direct payment under the Act or the SSPA. Such services include, but are not limited to, representing the claimant at any hearing or proceeding before the Agency or before a Federal court.

We also propose to modify our current rules to clarify that we may issue IRS Form 1099–MISC to both individuals and entities for payments over the annual aggregate of $600. We will gather additional information during the registration process to simplify our compliance with the applicable Internal Revenue Service's regulation, 26 CFR 1.6045–5.

We propose to include these changes in §§ 404.1703, 404.1713, 404.1730, 416.1503, 416.1513, and 416.1530.

New Requirements to Use Form SSA–1696 to Appoint or Revoke the Appointment of a Representative and to Waive a Fee, Direct Payment of a Fee, or Both

We propose to require that a claimant use Form SSA–1696 to appoint or revoke the appointment of a representative. Similarly, we propose to require that a representative use Form SSA–1696 when the representative withdraws from representing a claimant. Currently, when a claimant appoints a representative using Form SSA–1696, we require only non-attorney representatives to sign the Form SSA–1696. However, we are moving toward an electronic process that will require the ''electronic signature'' of professional representatives, including attorneys, on the Form SSA–1696. To make the paper process as consistent as possible with the electronic process we envision, we propose to require both the signature of the claimant and the signature of any representative, including an attorney representative, on the paper Form SSA–1696 for the appointment of a representative. Making this change now will permit a seamless transition to the electronic process in the future.

We also propose to require a representative to use the Form SSA–1696 to waive a fee for representing the claimant before us, to waive direct payment of the fee, or both. By standardizing the transaction for these situations to one commonly-used form, we will simplify the process for our claimants and their representatives, and we will be able to manage the appointment, fee authorization, and fee payment processes more efficiently. We also propose to clarify our policies about when a claimant's appointment of a representative begins and ends.

We propose to include these rules in §§ 404.1707, 404.1712, 404.1732, 416.1507, 416.1512, and 416.1532.

Internet Appeals

We propose to require professional representatives to submit certain requests for administrative appeal electronically at the times and in the manner that we prescribe, e.g., through the Internet. Claimants who are unrepresented or who are represented by individuals who are not classified as professional representatives may continue to file certain requests for reconsideration or an ALJ hearing by submitting either paper forms at one of our offices or using the electronic media we prescribe. We currently are making our Internet Appeals Web portal available for this purpose. That Web portal, which is now being voluntarily used by representatives to file requests for reconsideration and ALJ hearings, can be found at *https://secure.ssa.gov/apps6z/iAppeals/ap001.jsp.*

By requiring professional representatives to file certain requests for appeal with us electronically, we are following precedent set in the Federal court system. According to the Federal

judiciary's Case Management and Electronic Case Files System, as of February 2008, electronic filing systems are in use in 99% of Federal courts, over 31 million cases are maintained on these systems, and more than 320,000 users have filed documents over the Internet. Requiring professional representatives to file certain requests for reconsideration or an ALJ hearing via the Internet is a cost-effective measure that we expect will increase our efficiency and help reduce the disability determination backlog.

We do not expect this requirement to impose a burden on professional representatives. Representatives currently use several of our online services extensively, including the online Disability Report and the Electronic Records Express (ERE) system, which allows representatives to submit evidence to the electronic folder. We implemented the Internet Appeals software application in December 2007, and, to date, representatives have filed almost 100,000 appeals electronically. We may expand this electronic process to include appeals to the Appeals Council at a later time.

We propose to include these rules in §§ 404.901, 404.909, 404.910, 404.933, 404.934, 404.1740, 416.1401, 416.1409, 416.1410, 416.1433, 416.1434, and 416.1540.

New Affirmative Duties for Representatives

We propose to add a new affirmative duty for professional representatives and individuals working on their behalf to provide us with specific attestations to ensure they know, understand, and will comply with our rules and regulations. As indicated above, these attestations will be provided during the access registration process. We also propose to add a new affirmative duty for professional representatives, and for non-professional representatives who choose to file the Appointment of Representative form electronically. These representatives must keep, and provide to us upon request, paper copies of the Form SSA–1696 with the original signature of the claimant, the electronic signature of the representative, and the respective dates of the signing. Further, we will require entities to maintain, and provide to us on request, a signed statement from each attorney, eligible non-attorney, and employee. In the statement, they must aver that they are performing all representational services on behalf of the entity, that any fees should be paid directly to the entity, and that they will receive compensation directly from the entity.

We also propose to place an affirmative duty on professional representatives to file certain requests for reconsideration or an ALJ hearing using the electronic media that we prescribe. However, if a representative disregards or violates our rules or regulations, we will not penalize the claimant. We will not reject or delay a claimant's request for appeal or process it differently than a request for appeal submitted correctly.

Violation of these affirmative duties may subject the representative to sanctions under 20 CFR 404.1745 and 416.1545. We may ask representatives to provide us with forms, documents, copies of signed statements, and other information to confirm that representatives are complying with our rules. We expect that these changes will create safeguards against fraudulent activity.

Consistent with our proposal to recognize entities as representatives and our recognition that the business practices of those who represent claimants have changed significantly, we propose to clarify that an attorney or a non-attorney whom a claimant has not appointed as his representative but who works for or on behalf of the claimant's appointed representative and helps represent the claimant in his claim before us will also be subject to our rules of conduct and standards of responsibility and our sanctions procedures in 20 CFR 404.1740–404.1799 and 416.1540–416.1599.

We propose to add these rules in §§ 404.1703, 404.1740, 416.1503, and 416.1540.

New Prohibited Actions for Representatives

We propose to revise our list of prohibited actions to include three additional items: refusing to comply with any of our regulations, violating any section of the Act for which a criminal or civil monetary penalty is prescribed, and assisting another individual whom we have suspended or disqualified. Violation of these prohibited actions may subject the representative, or an attorney or a non-attorney whom a claimant has not appointed as his representative but who works for or on behalf of the claimant's appointed representative and helps represent the claimant in his claim before us, to sanctions under §§ 404.1745 and 416.1545. We propose to add these rules in §§ 404.1740 and 416.1540.

Other Changes

We propose several additional changes. First, we propose to clarify that we may reject a claimant's appointment of a representative if the representative does not meet our requirements and that we will notify the claimant and the claimant's representative of our decision. §§ 404.903, 404.1705, 416.1403, and 416.1505. Our refusal to accept an appointment of a representative is not an administrative action subject to our administrative review process.

Second, we propose to add several new definitions, revise existing definitions, and to move existing definitions from §§ 404.1770 and 416.1570 to §§ 404.1703 and 416.1503. These definitions include the terms: ''disqualify,'' ''electronic media,'' ''Federal agency,'' ''Federal program,'' ''fee petition,'' ''person,'' ''principal representative,'' ''professional representative,'' and ''representative.'' We also propose to add a new definition for ''initial disability claim'' to §§ 404.901 and 416.1401.

Third, we propose in several sections to change references from the Deputy Commissioner for Disability and Income Security Programs to the General Counsel and references from the Associate Commissioner for Hearings and Appeals to the Deputy Commissioner for Disability Adjudication and Review to reflect a recent reorganization and a new delegation of authority. Finally, we propose to make other minor conforming changes.

Clarity of These Rules

Executive Order 12866, as amended, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

When Will We Start To Use These Rules?

We will not use these rules until we evaluate the public comments we

receive on them, determine whether they should be issued as final rules, and issue final rules in the **Federal Register**. If we publish final rules, we will explain in the preamble how we will apply them, and summarize and respond to the public comments. Until the effective date of any final rules, we will continue to use our current rules.

Regulatory Procedures

Executive Order 12866, as Amended

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866, as amended. Therefore, they were reviewed by OMB.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities. Although these proposed rules would require small entities to provide us with certain information and to use available electronic services in certain instances, small entities would not be disadvantaged or limited in their ability to compete with larger competitors. Additionally, these proposed rules do not place significant costs on small entities. It is anticipated that small entities that take advantage of our electronic service delivery may find slight cost savings as a result of increased efficiency. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These regulations, which propose several revisions to our rules on Representation of Parties, contain reporting requirements in the regulation sections listed below. For some sections, we previously accounted for the public reporting burdens in the Information Collection Requests for the various forms the public uses to submit the information to SSA. Consequently, in those cases we inserted a 1-hour placeholder burden to these sections. For those sections whose public reporting burdens are not covered by an existing OMB-approved form, we provided burden estimates.

Regulation sections and description	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)
404.612; 404.1710; 416.315; 416.1510—Principal representatives may sign and file applications with SSA on beneficiaries' behalf.	—	—	—	1 (placeholder).
404.909; 404.910; 404.1740; 416.1409; 416.1410; 416.1540—Disability claimants who wish to request a reconsideration must do so in writing within 60 days after notice of initial determination is received (unless SSA grants a time extension). Parties filing on their own behalf or using non-professional representatives may use SSA's Internet Web site to submit the request; professional representatives are required to do so.	—	—	—	1 (placeholder).
404.933; 404.934; 416.1433; 416.1434—Disability claimants who wish to request a hearing before an administrative law judge must do so in writing within 60 days after notice of the previous determination/decision is received (unless SSA grants a time extension). Parties filing on their own behalf or using non-professional representatives may use SSA's Internet Web site to submit the request; professional representatives are required to do so.	—	—	—	1 (placeholder).
404.1740; 416.1540—Professional representatives for disability claimants must always use an SSA-approved form on SSA's Internet site to request a reconsideration or a hearing before an administrative law judge.	—	—	—	1 (placeholder).
404.1705; 404.1707; 404.1712; 416.1505; 416.1507; 416.1512; 408.1101—Procedures for beneficiary to appoint, change, revoke, or reappoint a representative and for representatives to accept appointment as representative or withdraw as representative.	—	—	—	1 (placeholder).
404.1705; 404.1713; 404.1730; 416.1505; 416.1530; 416.1513—Representative must register with SSA to receive payment.	—	—	—	1 (placeholder).
404.1712; 404.1720; 404.1725; 404.1730; 416.1512; 416.1520; 416.1525; 416.1530—Procedures for representative to sign fee petition; and Representative must file a request with us to charge or receive a fee; and to obtain approval of a fee representative must file a written request with SSA.	—	—	—	1 (placeholder).
404.1715; 416.1515—Principal representatives are responsible for informing other representatives of the beneficiary about any information SSA sent to the principal representative.	56,000	5	2	9,333.
404.1728; 416.1528—If representatives provide services to beneficiaries in connection with a hearing/court proceeding before SSA and wants to charge for those services, they must file a request and provide necessary documentation.	—	—	—	1 (placeholder).
404.1732; 415,1532—Representatives may waive the right to charge and collect a fee, direct payment, or both.	—	—	—	1 (placeholder).
404.1740; 416.1540—Procedures requiring representatives to maintain hard copy of certain forms with signatures and dates of signing.	—	—	—	1 (placeholder).
404.1755; 416.1555—If SSA files charges against a representative, the representative may contest these charges.	(1)	—	—	—
404.1780; 416.1580—If a party files a brief or other written statement with the Appeals Council, the party should send a copy to the opposite party and certify that they did so.	(1)	—	—	—
404.1799; 416.1599—Representatives who were suspended or disqualified should submit any evidence they want the Appeals Council to consider along with their request to be reinstated as a representative.	(1)	—	—	—

Regulation sections and description	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)
422.515—When SSA references "forms" for withdrawal, reconsideration, other appeals, and appointment of representatives, this refers to traditional printed forms, computer screens completed by SSA employees, or electronically submitted forms.	—	—	—	1 (placeholder).

[1] Less than 10 respondents.

SSA submitted an Information Collection Request to OMB for clearance. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. If you would like to submit comments, please send them to the following locations:

Office of Management and Budget, Attn: Desk Officer for SSA, Fax Number: 202–395–6974, E-mail address: *OIRA_Submission@omb.eop.gov*

Social Security Administration, Attn: Reports Clearance Officer, 1333 Annex Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–965–6400, E-mail address: *OPLM.RCO@ssa.gov*.

You can submit comments on the paperwork burdens associated with this rule for up to 60 days after publication of this notice; however, they will be most useful if you send them to SSA within 30 days of publication. This does not affect the deadline for the public to comment to SSA on the proposed regulations. To receive a copy of the OMB clearance package, contact the SSA Reports Clearance Office using any of the above contact methods. We prefer to receive comments by e-mail or fax.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income; and 96.020, Special Benefits for Certain World War II Veterans)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Penalties, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 408

Administrative practice and procedure, Aged, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI), Veterans.

20 CFR Part 416

Administrative practice and procedure, Penalties, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

20 CFR Part 422

Administrative practice and procedure, Organization and functions (Government agencies), Social Security.

Dated: August 27, 2008.

Michael J. Astrue,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR parts 404, 408, 416, and 422 as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart G—[Amended]

1. The authority citation for subpart G of part 404 continues to read as follows:

Authority: Secs. 202(i), (j), (o), (p), and (r), 205(a), 216(i)(2), 223(b), 228(a), and 702(a)(5) of the Social Security Act (42 U.S.C. 402(i), (j), (o), (p), and (r), 405(a), 416(i)(2), 423(b), 428(a), and 902(a)(5)).

2. Amend § 404.612 by adding paragraph (h) to read as follows:

§ 404.612 Who may sign an application.

* * * * *

(h) Your principal representative (see §§ 404.1705 and 404.1707) may sign and file your application with us. If a principal representative signs an application on your behalf, you are responsible for the accuracy of the information you provide.

Subpart J—[Amended]

3. The authority citation for subpart J of Part 404 continues to read as follows:

Authority: Secs. 201(j), 204(f), 205(a), (b), (d)–(h), and (j), 221, 223(i), 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)–(h), and (j), 421, 423(i), 425, and 902(a)(5)); sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

4. Amend § 404.901 by adding a definition in alphabetical order to read as follows:

§ 404.901 Definitions.

* * * * *

Initial disability claim means:

(1) An application for benefits that is based on whether you are disabled under title II of the Act, or

(2) An application for supplemental security income payments that is based on whether you are disabled or blind under title XVI of the Act.

(3) For purposes of this subpart, the term ''initial disability claim'' does not include a continuing disability review or an age-18 redetermination.

* * * * *

5. Amend § 404.903 by revising paragraph (g) to read as follows:

§ 404.903 Administrative actions that are not initial determinations.

* * * * *

(g) Refusing to recognize, disqualifying, or suspending a person, as defined in § 404.1703, from acting as your representative in a proceeding before us (see §§ 404.1705 and 404.1745);

* * * * *

6. Amend § 404.909 by revising the section heading and paragraphs (a) introductory text and (a)(2), and by removing the heading of paragraph (b), to read as follows:

§ 404.909 How to request reconsideration in claims other than those that involve a denial of an initial disability claim based on medical factors.

(a) We will reconsider an initial determination, other than one that involves a denial of your initial disability claim based on medical factors (see § 404.910), if you or any other party to the reconsideration files a written request—

* * * * *

(2) At one of our offices, the Veterans Administration Regional Office in the Philippines, or an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry,

or at least five years of railroad service accruing after December 31, 1995.

* * * * *

7. Add a new § 404.910 to read as follows:

§ 404.910 How to request reconsideration in an initial disability claim that is denied based on medical factors.

(a) If you file an initial disability claim, we will reconsider an initial determination that denies your claim based on medical factors if you or any other party to the reconsideration files a written request within 60 days after the date you receive notice of the initial determination and you make your request in accordance with paragraphs (b) or (c) (or within the extended time period if we extend the time as provided in paragraph (d)) of this section.

(b) If you have not appointed a representative, or if your representative is not a professional representative, as defined in § 404.1703, you may file your written request for reconsideration either through the electronic media we prescribe, at one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

(c) If your representative is a professional representative, as defined in § 404.1703, your professional representative must file your written request for reconsideration with us through the electronic media that we prescribe, unless we waive this requirement.

(d) If you want a reconsideration of the initial determination that denies your initial disability claim based on medical factors, but do not request one in time, you may ask us for more time to request a reconsideration. Your request for an extension of time must be in writing and must give the reasons why the request for reconsideration was not filed within the stated time period. If you show us that you had good cause for missing the deadline, we will extend the time period. To determine whether good cause exists, we use the standards explained in § 404.911. You must file the request for an extension of time according to the procedures in paragraphs (b) or (c) of this section.

8. Amend § 404.933 by revising the section heading and paragraphs (a) introductory text and (b)(2) to read as follows:

§ 404.933 How to request a hearing before an administrative law judge in claims other than those that involve a denial of an initial disability claim based on medical factors.

(a) *Written request.* You may request a hearing on your claim, other than one that involves a denial of your initial disability claim based on medical factors (see § 404.934), by filing a written request. You should include in your request—

* * * * *

(b) * * *

(2) At one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

* * * * *

9. Add a new § 404.934 to read as follows:

§ 404.934 How to request a hearing before an administrative law judge in an initial disability claim that is denied based on medical factors.

(a) If we deny your reconsidered initial disability claim based on medical factors, you may request a hearing by filing a written request. You should include in your request—

(1) The name and social security number of the wage earner;

(2) The reasons you disagree with the previous determination or decision;

(3) A statement of additional evidence to be submitted and the date you will submit it; and

(4) The name and address of any designated representative.

(b) Your request for a hearing must be filed within 60 days after the date you receive notice of the previous determination or decision (or within the extended time period if we extend the time as provided in paragraph (e) of this section).

(c) If you have not appointed a representative, or if your representative is not a professional representative, as defined in § 404.1703, you may file your written request for a hearing either through the electronic media we prescribe, at one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

(d) If your representative is a professional representative, as defined in § 404.1703, your professional representative must file your written request for a hearing with us through the electronic media that we prescribe, unless we waive this requirement.

(e) If you have a right to a hearing with respect to a determination or decision that denies your initial disability claim based on medical factors, but you do not request one in time, you may ask for more time to make your request. The request for an extension of time must be in writing and it must give the reasons why the request for a hearing was not filed within the stated time period. If you show that you had good cause for missing the deadline, we will extend the time period. To determine whether good cause exists, we use the standards explained in § 404.911. You must file the request for an extension of time according to the procedures in paragraphs (b) or (c) of this section.

Subpart R—[Amended]

10. The authority citation for subpart R of part 404 continues to read as follows:

Authority: Secs. 205(a), 206, 702(a)(5), and 1127 of the Social Security Act (42 U.S.C. 405(a), 406, 902(a)(5), and 1320a–6); sec. 303, Pub. L. 108–203, 118 Stat. 493.

11. Amend § 404.1700 by revising the introductory text and paragraph (a) to read as follows:

§ 404.1700 Introduction.

You may appoint one or more individuals or entities to represent you in any of your dealings with us. This subpart explains, among other things—

(a) Who may be your representative and what your representative's qualifications must be;

* * * * *

12. Revise § 404.1703 to read as follows:

§ 404.1703 Definitions.

As used in this subpart—

Access registration means supplying us with personal information that we use to identify you, your representative, or an individual working on behalf of your representative, to authenticate and authorize you, your representative, or an individual working on behalf of your representative to do business with us.

Direct payment registration means supplying to us personal, financial institution, and business affiliation information that we use to authorize a representative under certain circumstances to receive direct payment of representative fees via electronic funds transfer.

Disqualify refers to an action that prohibits a person from participating in or appearing before a Federal agency or Federal program, regardless of how long

the prohibition lasts or the specific terminology used.

Electronic media means the electronic media that we prescribe for providing us information, registering with us, and filing with us certain applications, forms, and other documents.

Entity means any business, firm, or other association, including but not limited to partnerships, corporations, for-profit organizations, and not-for-profit organizations.

Federal agency refers to any authority of the Executive branch of the Government of the United States.

Federal program refers to any program established by an Act of Congress or administered in whole or in part by a Federal agency.

Fee petition means a written statement signed by the claimant's representative requesting the fee the representative wants to charge and collect for services the representative provided in pursuing the claimant's benefit rights in proceedings before us.

Past-due benefits means the total amount of benefits under title II of the Act that has accumulated to all beneficiaries because of a favorable administrative or judicial determination or decision, up to but not including the month the determination or decision is made. For purposes of calculating fees for representation, we determine past-due benefits before any applicable reduction under section 1127 of the Act (for receipt of benefits for the same period under title XVI). Past-due benefits do not include:

(1) Continued benefits paid pursuant to § 404.1597a; or

(2) Interim benefits paid pursuant to section 223(h) of the Act.

Person means an individual or an entity.

Principal representative means an attorney who meets all of the requirements of § 404.1705(a), an individual other than an attorney who meets all of the requirements of § 404.1705(b), or an entity that meets all of the requirements under § 404.1705(b), who has been appointed to represent you in dealings with us and who is responsible for disseminating information and requests from us to you and your other representatives, if any.

Professional representative means any attorney, any individual other than an attorney, or any entity that holds itself out to the public as providing representational services (see § 404.1735) before us, regardless of whether the representative charges or collects a fee for providing the representational services.

Representative means an attorney who meets all of the requirements of § 404.1705(a), an individual other than an attorney who meets all of the requirements of § 404.1705(b), or an entity that meets all of the requirements of § 404.1705(b), whom you appoint to represent you in dealings with us. For purposes of §§ 404.1740 through 404.1799, the term *representative* also includes an attorney or a non-attorney whom you have not appointed as your representative under the previous sentence but who works for or on behalf of an appointed representative and helps represent you in your claim before us.

We, our(s), or *us* refers to the Social Security Administration.

You or *your(s)* refers to any individual claiming a right under the old-age, disability, dependents', or survivors' benefits program.

13. Amend § 404.1705 by removing the heading for paragraphs (a) and (b), revising paragraph (b) introductory text, and adding paragraphs (c) through (g) to read as follows:

§ 404.1705 Who may be your representative.

* * * * *

(b) You may appoint any person who is not an attorney to be your representative in dealings with us if the person—

* * * * *

(c) We may refuse to recognize your appointed representative if the representative does not meet our requirements. We will notify you and your appointed representative if we do not recognize your appointed representative.

(d) You may appoint more than one representative to represent you at the same time.

(e) You must have a principal representative. When you appoint only one representative, that representative is your principal representative. When you appoint more than one representative you must select one of your appointed representatives as your principal representative. Your principal representative is responsible for disseminating information and requests from us to you and your other representatives, if any, and for providing us information from you and about your claim. You may have only one principal representative at a time.

(f) If at any point you are represented by more than one representative and you have not appointed or do not have a principal representative, we will name one of your appointed representatives as your principal representative. You may appoint a different principal representative than the one we name by filing the appropriate form.

(g) Each of your representatives, as well as individuals working on their behalf, must complete access registration with us in the manner we prescribe.

14. Revise § 404.1707 to read as follows:

§ 404.1707 How you appoint and revoke the appointment of a representative.

(a) You must use the version of the form we prescribe, electronic or paper, to appoint or revoke the appointment of a representative.

(1) If your representative is not a professional representative, and your representative does not want to deal with us through the electronic media we prescribe, we will recognize your appointment of a representative if—

(i) Both you and your representative sign the paper form we prescribe;

(ii) You choose a principal representative on the form we prescribe at the time of the appointment; and

(iii) You or your representative files the signed form with us at one of our offices if you have initially filed a claim or have requested reconsideration; with the hearing office if you have requested a hearing; or with the Appeals Council if you have requested a review of the administrative law judge's decision.

(2) If your representative is a professional representative, or if your representative is not a professional representative but wants to do business with us through the electronic media we prescribe, we will recognize your appointment of a representative if—

(i) Your representative electronically signs the form we prescribe, prints the electronically signed form, and you sign the printed copy of the form;

(ii) You choose a principal representative on the form we prescribe at the time of the appointment; and

(iii) Your representative files the electronic form in the manner we prescribe.

(3) If we do not make the electronic form available or we prescribe that the electronic form is not required, then we will recognize your appointment of a professional representative according to the procedures in paragraph (a)(1) of this section.

(b) Each time you change your principal representative, you must file a new version of the form we prescribe.

(c) If at any point you are represented by more than one representative and you have not appointed or do not have a principal representative, we will name one of your appointed representatives as your principal representative. You may appoint a different principal representative than the one we name by filing the appropriate form.

(d) You must file the form we prescribe with us to revoke the appointment of a representative. The date of the revocation is the date on which you file the form with us. We will notify you and your representative that you revoked your representative's appointment.

15. Amend § 404.1710 by revising paragraphs (a) introductory text and (b) and adding paragraph (c) to read as follows:

§ 404.1710 Authority of a representative.

(a) Your representative may, on your behalf—

* * * * *

(b) Your principal representative may also sign and file an application on your behalf for rights or benefits under title II of the Act, as described in § 404.612(h).

(c) If you appoint an entity as your representative, any document related to the claim that is signed by a registered employee of the entity is binding on that entity, even if the employee's association with the entity ends.

16. Add a new § 404.1712 to read as follows:

§ 404.1712 When the appointment of your representative begins and ends.

(a) The appointment of your representative begins on the date that you and your representative sign the form we prescribe appointing your representative as described in § 404.1707. However, we will not recognize your appointment of a representative or deal with your representative until you or your representative file(s) the signed form with us.

(b) If your appointed representative is an individual, the individual's authority continues until the earliest of the following actions occur—

(1) You file the prescribed form with us revoking the appointment of your representative;

(2) Your representative files the prescribed form with us withdrawing as your representative;

(3) We have made a final determination or decision on your claim and the claims of any auxiliary beneficiary, the period in which you or your representative could appeal our determination or decision has ended, and you or your representative, or the auxiliary beneficiary, if any, did not file an appeal before the end of that period;

(4) Your representative files a fee petition requesting our authorization to charge and collect a fee (see §§ 404.1720 and 404.1725);

(5) We have closed out any application that was started by you or on your behalf but was not pursued within the time period we prescribe;

(6) We disqualify or suspend your representative; or

(7) Your representative dies.

(c) If your appointed representative is an entity, the entity's authority continues until the earliest of the following actions occur—

(1) You file the prescribed form with us revoking the appointment of your representative;

(2) Your representative files the prescribed form with us withdrawing as your representative.

(3) We have made a final determination or decision on your claim and the claims of any auxiliary beneficiary, the period in which you or your representative could appeal our determination or decision has ended, and you or your representative, or the auxiliary beneficiary, if any, did not file an appeal before the end of that period;

(4) Your representative files a fee petition requesting our authorization to charge and collect a fee (see §§ 404.1720 and 404.1725);

(5) We have closed out any application that was started by you or on your behalf but was not pursued within the time period we prescribe;

(6) We disqualify or suspend your representative;

(7) The entity goes out of business; or

(8) The entity changes ownership or changes the services it provides, such that it no longer represents claimants before us.

(d) You may reappoint a representative by properly filing a new prescribed form with us in accordance with §§ 404.1705 and 404.1707.

17. Add a new § 404.1713 to read as follows:

§ 404.1713 Professional representatives.

(a) Professional representatives must conduct business with us electronically at the times and in the manner that we prescribe.

(b) Professional representatives, and individuals working on behalf of professional representatives on claims before us, must make certain attestations we require to ensure that each individual knows, understands, and will comply with our rules and regulations. Each of these individuals will make these attestations one time during the access registration process.

18. Revise § 404.1715 to read as follows:

§ 404.1715 Notice or request to a representative.

(a) We will send to you, your principal representative, and your other representatives, if any, all notices relating to the appointment of any of your representatives and the revocation or withdrawal of an appointment of any of your representatives. Notices sent in accordance with § 404.1730(c)(2)(i) will be sent to any representative who has not filed a written request for a fee in accordance with § 404.1730(c)(1).

(b) We will send only to your principal representative—

(1) Notices and copies of any administrative action, determination, or decision in your claim; and

(2) Requests for information or evidence in your claim.

(c) If your principal representative is an entity, we will send all notices, copies of any administrative action, determination, or decision in your claim, and requests for information to the individual who signed the appointment of representative form on behalf of the entity, until or unless the entity informs us of a different contact within the entity for this purpose.

(d) Your principal representative is responsible for informing other appointed representatives, if any, about any notices, administrative actions, determinations, decisions, or requests for information or evidence that we send to the principal representative. We will not send copies of notices, any administrative actions, determinations, decisions, or requests for information or evidence to any representative, except your principal representative.

(e) Any notice or request we send to your principal representative will have the same force and effect as if we sent it directly to you.

19. Amend § 404.1720 by revising paragraphs (a), (b)(1), (b)(3), (b)(4), (c) introductory text, (c)(3), the first two sentences of paragraph (d)(1), and the first sentence of paragraph (d)(2)(i) to read as follows:

§ 404.1720 Fee for a representative's services.

(a) *General.* A representative may charge and receive a fee for providing you with services as a representative as provided in paragraph (b) of this section, or as provided in section 206(a)(2) of the Act.

(b) *Charging and receiving a fee under the fee petition process.* (1) A representative must file a written fee petition with us before the representative may charge or receive a fee for providing you with services.

* * * * *

(3) A representative must not charge or receive any fee unless we have approved it, and a representative must not charge or receive any fee that is more than the amount we approve.

(4) If the representative is an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 404.1717, or an entity that meets the requirements in § 404.1730(f) and the claimant is entitled to past-due benefits, we will pay the authorized fee, or a part of the authorized fee, directly to the attorney, eligible non-attorney, or eligible entity out of the past-due benefits, subject to the limitations described in § 404.1730(b)(1). If the representative is not an attorney, eligible non-attorney, or eligible entity, we assume no responsibility for the payment of any fee that we have authorized.

(c) *Notice of determination on the fee petition.* We will mail to both you and your representative at your last known addresses a written notice of what we decide about the fee petition. We will state in the notice—

* * * * *

(3) That we are not responsible for paying the fee, except when we may pay an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 404.1717, or an entity that meets the requirements in § 404.1730(f), from past-due benefits; and

* * * * *

(d) *Review of fee petition determination*—(1) *Request filed on time.* We will review the decision we made about a fee petition if either you or your representative files a written request for the review through the electronic media we prescribe or at one of our offices within 30 days after the date of the notice of the fee determination. Either you or your representative, whoever requests the review, must mail a copy of the request to the other person. * * *

(2) *Request not filed on time.* (i) If you or your representative requests a review of the decision we made about a fee, but does so more than 30 days after the date of the notice of the fee determination, whoever makes the request must state in writing why it was not filed within the 30-day period. * * *

* * * * *

20. Amend § 404.1725 by revising the section heading, paragraphs (a) introductory text, (a)(2) through (a)(6), the heading for paragraph (b), and paragraph (b)(1)(vii) to read as follows:

§ 404.1725 Request for approval of a fee petition.

(a) *Filing a written fee petition.* Unless your representative's fee is approved pursuant to section 206(a)(2) of the Act, in order for your representative to obtain approval of a fee for services your representative performed in dealings with us, your representative must file a written fee petition through the electronic media we prescribe or at one of our offices. This should be done after the proceedings in which your representative represented you are completed. The request must contain—

* * *

(2) A list of the services your representative provided and the amount of time your representative spent on each type of service;

(3) The amount of the fee your representative wants to charge for the services;

(4) The amount of fee your representative wants to request or charge for representing you in the same matter before any State or Federal court;

(5) The amount of and a list of any expenses your representative incurred for which your representative has been paid or expects to be paid;

(6) A description of the special qualifications which enabled your representative, if not an attorney, to give valuable help in connection with your claim; and * * *

(b) *Evaluating a request for approval of a fee petition.*

(1) * * *

(vii) The amount of fee the representative requests for the representative's services, including any amount authorized or requested before, but not including the amount of any expenses the representative incurred.

* * * * *

21. Amend § 404.1728 by revising paragraph (a) to read as follows:

§ 404.1728 Proceedings before a State or Federal court.

(a) *Representation of a party in court proceedings in fee petitions.* We will not consider any service the representative gave you in any proceeding before a State or Federal court to be services as a representative in dealings with us. However, if the representative also has given service to you in the same connection in any dealings with us, the representative must specify what, if any, portion of the fee the representative wants to charge is for services performed in dealings with us. If the representative charges any fee for those services, the representative must file the request and furnish all of the information required by § 404.1725.

* * * * *

22. Revise § 404.1730 to read as follows:

§ 404.1730 Payment of fees.

(a) *Fees allowed by a Federal court in fee petitions.* We will pay a representative who is an attorney out of your past-due benefits the amount of the fee allowed by a Federal court in a proceeding under title II of the Act. This payment is subject to the limitations described in paragraph (b)(1) of this section.

(b) *Fees we may authorize for payment in fee petitions*—(1) *Attorneys, eligible non-attorneys, and eligible entities.* Except as provided in paragraphs (c) and (e) of this section, if we make a determination or decision in your favor and you were represented by an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 404.1717, or an entity that meets the requirements in paragraph (f) of this section, and as a result of the determination or decision you have past-due benefits, we will pay the representative out of the past-due benefits, the smallest of the amounts in paragraphs (b)(1)(i) or (ii) of this section, less the amount of the assessment described in paragraph (d) of this section.

(i) Twenty-five percent of the total of the past-due benefits; or

(ii) The amount of the fee that we set.

(2) *Persons not eligible for direct payment.* If the representative is a non-attorney who is not eligible to participate in the direct payment demonstration project or an entity that is not eligible for direct payment of the fee, we assume no responsibility for the payment of any fee that we have authorized. We will not deduct the fee from your past-due benefits.

(c) *Time limit for filing request for approval of fee petition to obtain direct payment.* (1) To receive direct payment of a fee from your past-due benefits, a representative who is an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 404.1717, or an entity that meets the requirements in paragraph (f) of this section should file a request for approval of a fee or a written notice of the intent to file a request within 60 days of the date we mail the notice of the favorable determination or decision. The representative should file the request or written notice through the electronic media we prescribe or at one of our offices. Your representative must send you a copy of any request for approval of a fee, any written notice of the intent to file a request for approval of a fee, or any request for an extension of time filed with us.

(2)(i) If no request is filed within 60 days of the date we mail the notice of the favorable determination or decision, we will mail a written notice to you and

your representative at your last known addresses. The notice will inform you and the representative that unless the representative files, within 20 days from the date of the notice, a written request for approval of a fee under § 404.1725, or a written request for an extension of time showing good cause (see § 404.911), we will pay all the past-due benefits to you.

(ii) Your representative must send you a copy of any request made to us for an extension of time. If the request is not filed within 20 days of the date of the notice we send under paragraph (c)(2)(i) of this section, or by the last day of any extension we approved, we will pay all past-due benefits to you. We must approve any fee your representative charges after that time, but the collection of any approved fee is a matter between you and your representative.

(d) *Assessment when we pay a fee directly to a representative.* (1) Whenever we pay a fee directly to a representative from past-due benefits, we impose an assessment on the representative.

(2) The amount of the assessment is equal to the lesser of:

(i) The product we obtain by multiplying the amount of the fee we are paying to the representative by the percentage rate the Commissioner of Social Security determines is necessary to achieve full recovery of the costs of determining and paying fees directly to representatives, but not in excess of 6.3 percent; and

(ii) The maximum assessment amount. The maximum assessment amount was initially set at $75, but by law is adjusted annually to reflect the increase in the cost-of-living. (See §§ 404.270 through 404.278 for an explanation of how the cost-of-living adjustment is computed.) If the adjusted amount is not a multiple of $1, we round down the amount to the next lower $1, but the amount will not be less than $75. We will announce in the **Federal Register** any increase in the maximum assessment amount and explain how the increase was determined.

(3) We collect the assessment by subtracting it from the amount of the fee to be paid to the representative. The representative who is subject to an assessment may not, directly or indirectly, request or otherwise obtain reimbursement of the assessment from you.

(e) *Direct payment registration.* (1) To receive direct payment, the representative must first complete direct payment registration with us in the form and manner that we prescribe.

(2) We will only make direct payment of fees via electronic funds transfer.

(f) *Direct payment to entities.* We will only make direct payment to an entity that provides the following attestations in its request for direct payment of fees:

(1) The entity must attest that it is in possession of a signed statement from each attorney or non-attorney who has performed any representational services for the claim in question that includes the following:

(i) The attorney or non-attorney has performed all representational services on behalf of the entity,

(ii) Any fees paid pursuant to the services the attorney or non-attorney have provided should be paid directly to the entity, and

(iii) The attorney or non-attorney representative receives compensation for the services provided directly from the entity.

(2) The entity must attest that all individuals who have provided representational services on the claim in question are individuals who qualify for direct payment under the Act or the direct payment demonstration project, as defined in § 404.1717.

23. Add a new § 404.1732 to read as follows:

§ 404.1732 Waiver of fee or direct payment, or both.

(a) Your representative may choose to waive the right to charge and receive a fee. An otherwise eligible representative who wishes to charge and receive a fee may waive the right to direct payment. A representative who waives the right to direct payment does not automatically waive the right to charge and receive a fee.

(b) Your representative must file a form we prescribe to waive direct payment of the fee.

(c) A waiver of the right to charge and receive a fee or of direct payment, or both, will apply to fees approved by a Federal court, unless it is otherwise specifically noted on the form completed in accordance with paragraph (b) of this section.

(d) If you have appointed an entity as your representative, any registered employee of the entity may sign the form completed in accordance with paragraph (b) of this section to waive the fee or direct payment, or both, on behalf of the entity.

24. Amend § 404.1740 by revising the first sentence of paragraph (a)(1), paragraph (b) introductory text, paragraph (b)(3) introductory text, the third sentence of paragraph (b)(3)(i), and the second sentence of paragraph (b)(3)(ii), adding paragraphs (b)(3)(iii) and (b)(4), revising paragraphs (c) introductory text, (c)(4), (c)(6), and (c)(7)(iii), and adding paragraphs (c)(8) through (c)(13) to read as follows:

§ 404.1740 Rules of conduct and standards of responsibility for representatives.

(a) * * * (1) All persons acting on behalf of a party seeking a statutory right or benefit must, in their dealings with us, faithfully execute their duties as agents and fiduciaries of a party.

* * *

(b) *Affirmative duties.* A representative must, in conformity with the regulations setting forth our existing duties and responsibilities and those of claimants (see § 404.1512 in disability and blindness claims):

* * * * *

(3) Conduct the representative's dealings in a manner that furthers the efficient, fair, and orderly conduct of the administrative decision-making process, including duties to:

(i) * * *This includes knowing the significant issue(s) in a claim and having a working knowledge of the applicable provisions of the Social Security Act, as amended, the regulations and the Rulings;

(ii) * * * This includes providing prompt and responsive answers to requests from the Agency for information pertinent to processing of the claim; and

(iii) Maintain a paper copy of the form described in § 404.1707(a) that reflects the representative's and the claimant's signatures and respective signature dates appointing the representative, and maintain copies of the signed attestations described in § 404.1730(f), and provide paper copies to us on request.

(4) If the representative is a professional representative, conduct business with us electronically at the times and in the manner that we prescribe when submitting any written request for reconsideration or a hearing before an administrative law judge on an initial disability claim that was based on medical factors.

(c) *Prohibited actions.* A representative must not:

* * * * *

(4) Through the representative's own actions or omissions, unreasonably delay or cause to be delayed, without good cause (see § 404.911(b)), the processing of a claim at any stage of the administrative decision-making process;

* * * * *

(6) Attempt to influence, directly or indirectly, the outcome of a decision, determination or other administrative action by offering or granting a loan,

gift, entertainment or anything of value to a presiding official, Agency employee or witness who is or may reasonably be expected to be involved in the administrative decisionmaking process, except as reimbursement for legitimately incurred expenses or lawful compensation for the services of an expert witness retained on a non-contingency basis to provide evidence;

(7) * * *

(iii) Threatening or intimidating language, gestures or actions directed at a presiding official, witness or Agency employee which results in a disruption of the orderly presentation and reception of evidence;

(8) Violate any section of the Social Security Act for which a criminal or civil monetary penalty is prescribed;

(9) Refuse to comply with any of our rules or regulations;

(10) Suggest, assist, or direct another person to violate our rules or regulations;

(11) Advise any claimant or beneficiary not to comply with any of our rules and regulations;

(12) Assist another person whom we have suspended or disqualified; or

(13) Fail to comply with our decision regarding sanctions.

25. Amend § 404.1750 by revising paragraphs (a) and (d) to read as follows:

§ 404.1750 Notice of charges against a representative.

(a) The General Counsel (or other official the Commissioner may designate), or his or her designee, will prepare a notice containing a statement of charges that constitutes the basis for the proceeding against the representative.

* * * * *

(d) The General Counsel (or other official the Commissioner may designate), or his or her designee, may extend the 30-day period for good cause in accordance with § 404.911.

* * * * *

26. Revise § 404.1755 to read as follows:

§ 404.1755 Withdrawing charges against a representative.

The General Counsel (or other official the Commissioner may designate), or his or her designee, may withdraw charges against a representative. We will do this if the representative files an answer, or we obtain evidence, that satisfies us that we should not suspend or disqualify the representative from acting as a representative in dealings with us. When we consider withdrawing charges brought under § 404.1745(d) or (e) based on the representative's assertion that, before or after our filing of charges, the representative has been reinstated to practice by the court, bar, or Federal program or Federal agency that suspended, disbarred, or disqualified the representative, the General Counsel (or other official the Commissioner may designate), or his or her designee, will determine whether such reinstatement occurred, whether it remains in effect, and whether he or she is reasonably satisfied that the representative will in the future act in accordance with the provisions of section 206(a) of the Act and our rules and regulations. If the representative proves that reinstatement occurred and remains in effect and the General Counsel, or his or her designee, is so satisfied, the General Counsel, or his or her designee, will withdraw those charges. The action of the General Counsel, or his or her designee, regarding withdrawal of charges is solely that of the General Counsel (or other official the Commissioner may designate), or his or her designee, and is not reviewable, or subject to consideration in decisions made under §§ 404.1770 and 404.1790. If we withdraw the charges, we will notify the representative by mail at the representative's last known address.

27. Amend § 404.1765 by revising paragraphs (a), (b)(1), and (e), the first sentence of paragraph (g)(2), and paragraphs (i), (l), and (m) to read as follows:

§ 404.1765 Hearing on charges.

(a) *Holding the hearing.* If the General Counsel (or other official the Commissioner may designate), or his or her designee, does not take action to withdraw the charges within 15 days after the date on which the representative filed an answer, we will hold a hearing and make a decision on the charges.

(b) *Hearing officer.* (1) The Deputy Commissioner for Disability Adjudication and Review (or other official the Commissioner may designate), or his or her designee, will assign an administrative law judge, designated to act as a hearing officer, to hold a hearing on the charges.

* * * * *

(e) *Parties.* The representative against whom charges have been made is a party to the hearing. The General Counsel (or other official the Commissioner may designate), or his or her designee, will also be a party to the hearing.

* * * * *

(g) *Conduct of the hearing.* * * *

(2) If the representative did not file an answer to the charges, the representative has no right to present evidence at the hearing. * * *

* * * * *

(i) *Witnesses.* Witnesses who testify at the hearing must do so under oath or affirmation. Either the representative or a person representing the representative may question the witnesses. The other party and that party's representative must also be allowed to question the witnesses. The hearing officer may also ask questions as considered necessary, and will rule upon any objection made by either party about whether any question is proper.

* * * * *

(l) *Representation.* The representative, as the person charged, may appear in person and may be represented by an attorney or other representative. The General Counsel (or other official the Commissioner may designate), or his or her designee, will be represented by one or more attorneys from the Office of the General Counsel.

(m) *Failure to Appear.* If the representative or the other party to the hearing fails to appear after being notified of the time and place, the hearing officer may hold the hearing anyway so that the party present may offer evidence to sustain or rebut the charges. The hearing officer will give the other party who failed to appear an opportunity to show good cause for failure to appear. If the party fails to show good cause, the party is considered to have waived the right to be present at the hearing. If the party shows good cause, the hearing officer may hold a supplemental hearing.

* * * * *

28. Amend § 404.1770 by revising paragraphs (a)(1), (a)(2), (a)(3) introductory text, (a)(3)(ii), (b)(2), and (b)(3) to read as follows:

§ 404.1770 Decision by hearing officer.

(a) *General.* (1) After the close of the hearing, the hearing officer will issue a decision or certify the case to the Appeals Council. The decision must be in writing, will contain findings of fact and conclusions of law, and be based upon the evidence of record.

(2) In deciding whether a person has been, by reason of misconduct, disbarred or suspended by a court or bar, or disqualified from participating in or appearing before any Federal program or agency, the hearing officer will consider the reasons for the disbarment, suspension, or disqualification action. If the action was taken for solely administrative reasons (e.g., failure to pay dues or to complete continuing legal education requirements), that will not disqualify the person from acting as

a representative before us. However, this exception to disqualification does not apply if the administrative action was taken in lieu of disciplinary proceedings (e.g., acceptance of a voluntary resignation pending disciplinary action). Although the hearing officer will consider whether the disbarment, suspension, or disqualification action is based on misconduct when deciding whether a person should be disqualified from acting as a representative before us, the hearing officer will not re-examine or revise the factual or legal conclusions that led to the disbarment, suspension, or disqualification.

(3) If the hearing officer finds that the charges against the representative have been sustained, he or she will either—

* * * * *

(ii) Disqualify the representative from acting as a representative in dealings with us until the representative may be reinstated under § 404.1799. Disqualification is the sole sanction available if the charges have been sustained because the representative has been disbarred or suspended from any court or bar to which the representative was previously admitted to practice or disqualified from participating in or appearing before any Federal program or agency, or because the representative has collected or received, and retains, a fee for representational services in excess of the amount authorized.

* * * * *

(b) *Effect of hearing officer's decision.* * * *

(2) If the final decision is that a person is disqualified from being a representative in dealings with us, the representative will not be permitted to represent anyone in dealings with us until authorized to do so under the provisions of § 404.1799.

(3) If the final decision is that a person is suspended for a specified period of time from being a representative in dealings with us, the representative will not be permitted to represent anyone in dealings with us during the period of suspension unless authorized to do so under the provisions of § 404.1799.

29. Amend § 404.1780 by revising paragraph (b) to read as follows:

§ 404.1780 Appeals Council's review of hearing officer's decision.

* * * * *

(b) If a party files a brief or other written statement with the Appeals Council, the party must send a copy to the opposing party and certify that the copy has been sent.

30. Amend § 404.1799 by revising paragraphs (b), (c), (d)(2), (d)(3), and (e), to read as follows:

§ 404.1799 Reinstatement after suspension or disqualification—period of suspension not expired.

* * * * *

(b) The suspended or disqualified person must submit any evidence the person wishes to have considered along with the request to be allowed to serve as a representative again.

(c) The General Counsel (or other official the Commissioner may designate), or his or her designee, upon notification of receipt of the request, will have 30 days in which to present a written report of any experiences with the suspended or disqualified person subsequent to that person's suspension or disqualification. The Appeals Council will make available to the suspended or disqualified person a copy of the report.

(d) * * *

(2) If a person was disqualified because the person had been disbarred or suspended from a court or bar, the Appeals Council will grant a request for reinstatement as a representative only if the criterion in paragraph (d)(1) of this section is met and the disqualified person shows that the person has been admitted (or readmitted) to and is in good standing with the court or bar from which the person had been disbarred or suspended.

(3) If a person was disqualified because the person had been disqualified from participating in or appearing before a Federal program or Federal agency, the Appeals Council will grant the request for reinstatement only if the criterion in paragraph (d)(1) of this section is met and the disqualified person shows that the person is now qualified to participate in or appear before that Federal program or Federal agency.

* * * * *

(e) The Appeals Council will mail a notice of its decision on the request for reinstatement to the suspended or disqualified person. It will also mail a copy to the General Counsel (or other official the Commissioner may designate), or his or her designee.

* * * * *

PART 408—SPECIAL BENEFITS FOR CERTAIN WORLD WAR II VETERANS

Subpart K—[Amended]

31. The authority citation for subpart K of part 408 continues to read as follows:

Authority: Secs. 702(a)(5) and 810(a) of the Social Security Act (42 U.S.C. 902(a)(5) and 1010(a)).

32. Amend § 408.1101 by revising paragraphs (a) and (b)(3) to read as follows:

§ 408.1101 Can you appoint someone to represent you?

(a) *General rules.* You may appoint one or more individuals or entities to represent you in any of your dealings with us. For purposes of this part, the rules on representation of parties in §§ 416.1500–416.1505, 416.1507–416.1515 and 416.1540–416.1599 of this chapter apply except as noted in paragraph (b) of this section.

(b) *Exceptions.* * * *

(3) In § 416.1507(a)(1)(iii), the words ''one of our offices'' are deemed to read ''any of the offices listed in § 408.1009(b).''

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart C—[Amended]

33. The authority citation for subpart C of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, and 1631(a), (d), and (e) of the Social Security Act (42 U.S.C. 902(a)(5), 1382, and 1383(a), (d), and (e)).

34. Amend § 416.315 by adding paragraph (d) to read as follows:

§ 416.315 Who may sign an application.

* * * * *

(d) Your principal representative (see §§ 416.1505 and 416.1507) may sign and file your application with us. If a principal representative signs an application on your behalf, you are responsible for the accuracy of the information you provide.

Subpart N—[Amended]

35. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

36. Amend § 416.1401 by adding a definition in alphabetical order to read as follows:

§ 416.1401 Definitions.

* * * * *

Initial disability claim means:

(1) An application for benefits that is based on whether you are disabled under title II of the Act, or

(2) An application for supplemental security income payments that is based

on whether you are disabled or blind under title XVI of the Act.

(3) For purposes of this subpart, the term ''initial disability claim'' does not include a continuing disability review or an age-18 redetermination.

* * * * *

37. Amend § 416.1403 by revising paragraph (a)(7) to read as follows:

§ 416.1403 Administrative actions that are not initial determinations.

(a) * * *

(7) Refusing to recognize, disqualifying, or suspending a person, as defined in § 416.1503, from acting as your representative in a proceeding before us (see §§ 416.1505 and 416.1545);

* * * * *

38. Amend § 416.1409 by revising the section heading and paragraph (a), and by removing the heading for paragraph (b), to read as follows:

§ 416.1409 How to request reconsideration in claims other than those that involve a denial of an initial disability claim based on medical factors.

(a) We will reconsider an initial determination, other than one that involves a denial of your initial disability claim based on medical factors (see § 416.1410), if you or any other party to the reconsideration files a written request within 60 days after the date you receive notice of the initial determination (or within the extended time period if we extend the time as provided in paragraph (b) of this section at one of our offices, the Veterans Administration Regional Office in the Philippines, or an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

* * * * *

39. Add a new § 416.1410 to read as follows:

§ 416.1410 How to request reconsideration in an initial disability claim that is denied based on medical factors.

(a) If you file an initial disability claim, we will reconsider an initial determination that denies your claim based on medical factors if you or any other party to the reconsideration files a written request within 60 days after the date you receive notice of the initial determination and you make your request in accordance with paragraphs (b) or (c) (or within the extended time period if we extend the time as provided in paragraph (d)) of this section.

(b) If you have not appointed a representative, or if your representative is not a professional representative, as defined in § 416.1503, you may file your written request for reconsideration either through the electronic media we prescribe, at one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

(c) If your representative is a professional representative, as defined in § 416.1503, your professional representative must file your written request for reconsideration with us through the electronic media that we prescribe, unless we waive this requirement.

(d) If you want a reconsideration of the initial determination that denies your initial disability claim based on medical factors, but do not request one in time, you may ask us for more time to request a reconsideration. Your request for an extension of time must be in writing and must give the reasons why the request for reconsideration was not filed within the stated time period. If you show us that you had good cause for missing the deadline, we will extend the time period. To determine whether good cause exists, we use the standards explained in § 416.1411. You must file the request for an extension of time according to the procedures in paragraphs (b) or (c) of this section.

40. Amend § 416.1433 by revising the section heading and paragraphs (a) introductory text and (b) to read as follows:

§ 416.1433 How to request a hearing before an administrative law judge in claims other than those that involve a denial of an initial disability claim based on medical factors.

(a) *Written request.* You may request a hearing on your claim, other than one that involves a denial of your initial disability claim based on medical factors (see § 416.1434), by filing a written request. You should include in your request—

* * * * *

(b) *When and where to file.* The request must be filed within 60 days after the date you receive notice of the previous determination or decision (or within the extended time period if we extend the time as provided in paragraph (c) of this section at one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

* * * * *

41. Add a new § 416.1434 to read as follows:

§ 416.1434 How to request a hearing before an administrative law judge in an initial disability claim that is denied based on medical factors.

(a) If we deny your reconsidered initial disability claim based on medical factors, you may request a hearing by filing a written request. You should include in your request—

(1) The name and Social Security number of the wage earner;

(2) The reasons you disagree with the previous determination or decision;

(3) A statement of additional evidence to be submitted and the date you will submit it; and

(4) The name and address of any designated representative.

(b) Your request for a hearing must be filed within 60 days after the date you receive notice of the previous determination or decision (or within the extended time period if we extend the time as provided in paragraph (e) of this section).

(c) If you have not appointed a representative, or if your representative is not a professional representative, as defined in § 416.1503, you may file your written request for a hearing either through the electronic media we prescribe, at one of our offices, at the Veterans Administration Regional Office in the Philippines, or at an office of the Railroad Retirement Board if you have 10 or more years of service in the railroad industry, or at least five years of railroad service accruing after December 31, 1995.

(d) If your representative is a professional representative, as defined in § 416.1503, your professional representative must file your written request for a hearing with us through the electronic media that we prescribe, unless we waive this requirement.

(e) If you have a right to a hearing with respect to a determination or decision that denies your initial disability claim based on medical factors, but you do not request one in time, you may ask for more time to make your request. The request for an extension of time must be in writing and it must give the reasons why the request for a hearing was not filed within the stated time period. If you show that you had good cause for missing the deadline, we will extend the time period. To determine whether good cause exists, we use the standards explained in § 416.1411. You must file the request for an extension of time

according to the procedures in paragraphs (b) or (c) of this section.

Subpart O—[Amended]

42. The authority citation for subpart O of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1127 and 1631(d) of the Social Security Act (42 U.S.C. 902(a)(5), 1320a–6 and 1383(d)); sec. 303, Pub. L. 108–203, 118 Stat. 493.

43. Amend § 416.1500 by revising the introductory text and paragraph (a) to read as follows:

§ 416.1500 Introduction.

You may appoint one or more individuals or entities to represent you in any of your dealings with us. This subpart explains, among other things—

(a) Who may be your representative and what your representative's qualifications must be;

* * * * *

44. Revise § 416.1503 to read as follows:

§ 416.1503 Definitions.

As used in this subpart—

Access registration means supplying us with personal information that we use to identify you, your representative, or an individual working on behalf of your representative, to authenticate and authorize you, your representative, or an individual working on behalf of your representative to do business with us.

Direct payment registration means supplying to us personal, financial institution, and business affiliation information that we use to authorize a representative under certain circumstances to receive direct payment of representative fees via electronic funds transfer.

Disqualify refers to an action that prohibits a person from participating in or appearing before a Federal agency or Federal program, regardless of how long the prohibition lasts or the specific terminology used.

Electronic media means the electronic media that we prescribe for providing us information, registering with us, and filing with us certain applications, forms, and other documents.

Entity means any business, firm, or other association, including but not limited to partnerships, corporations, for-profit organizations, and not-for-profit organizations.

Federal agency refers to any authority of the Executive branch of the Government of the United States.

Federal program refers to any program established by an Act of Congress or administered in whole or in part by a Federal agency.

Fee petition means a written statement signed by the claimant's representative requesting the fee the representative wants to charge and collect for services the representative provided in pursuing the claimant's benefit rights in proceedings before us.

Past-due benefits means the total amount of payments under title XVI of the Act, the Supplemental Security Income (SSI) program, including any Federally administered State payments, that has accumulated to you and your spouse because of a favorable administrative or judicial determination or decision, up to but not including the month the determination or decision is made. For purposes of calculating fees for representation, we first determine the SSI past-due benefits before any applicable reduction for reimbursement to a State (or political subdivision) for interim assistance reimbursement, and before any applicable reduction under section 1127 of the Act (for receipt of benefits for the same period under title II). We then reduce that figure by the amount of any reduction of title II or title XVI benefits that was required by section 1127. We do this whether the actual offset, as provided under section 1127, reduced the title II or title XVI benefits. Past-due benefits do not include:

(1) Continued benefits paid pursuant to § 416.996;

(2) Continued benefits paid pursuant to § 416.1336(b); or

(3) Interim benefits paid pursuant to section 1631(a)(8) of the Act.

Person means an individual or an entity.

Principal representative means an attorney who meets all of the requirements of § 416.1505(a), an individual other than an attorney who meets all of the requirements of § 416.1505(b), or an entity that meets all of the requirements under § 416.1505(b), who has been appointed to represent you in dealings with us and who is responsible for disseminating information and requests from us to you and your other representatives, if any.

Professional representative means any attorney, any individual other than an attorney, or any entity that holds itself out to the public as providing representational services (see § 416.1535) before us, regardless of whether the representative charges or collects a fee for providing the representational services.

Representative means an attorney who meets all of the requirements of § 416.1505(a), an individual other than an attorney who meets all of the requirements of § 416.1505(b), or an entity that meets all of the requirements of § 416.1505(b), whom you appoint to represent you in dealings with us. For purposes of §§ 416.1540 through 416.1599, the term *representative* also includes an attorney or a non-attorney whom you have not appointed as your representative under the previous sentence but who works for or on behalf of an appointed representative and helps represent you in your claim before us.

We, our(s), or *us* refers to the Social Security Administration.

You or *your(s)* refers to any individual or the eligible spouse of any individual claiming or receiving supplemental security income benefits.

45. Amend § 416.1505 by removing the heading for paragraphs (a) and (b), revising paragraph (b) introductory text, and adding paragraphs (c) through (g) to read as follows:

§ 416.1505 Who may be your representative.

* * * * *

(b) You may appoint any person who is not an attorney to be your representative in dealings with us if the person—

* * * * *

(c) We may refuse to recognize your appointed representative if the representative does not meet our requirements. We will notify you and your appointed representative if we do not recognize your appointed representative.

(d) You may appoint more than one representative to represent you at the same time.

(e) You must have a principal representative. When you appoint only one representative, that representative is your principal representative. When you appoint more than one representative you must select one of your appointed representatives as your principal representative. Your principal representative is responsible for disseminating information and requests from us to you and your other representatives, if any, and for providing us information from you and about your claim. You may have only one principal representative at a time.

(f) If at any point you are represented by more than one representative and you have not appointed or do not have a principal representative, we will name one of your appointed representatives as your principal representative. You may appoint a different principal representative than the one we name by filing the appropriate form.

(g) Each of your representatives, as well as individuals working on their behalf, must complete access

registration with us in the manner we prescribe.

46. Revise § 416.1507 to read as follows:

§ 416.1507 How you appoint and revoke the appointment of a representative.

(a) You must use the version of the form we prescribe, electronic or paper, to appoint or revoke the appointment of a representative.

(1) If your representative is not a professional representative, and your representative does not want to deal with us through the electronic media we prescribe, we will recognize your appointment of a representative if—

(i) Both you and your representative sign the paper form we prescribe;

(ii) You choose a principal representative on the form we prescribe at the time of the appointment; and

(iii) You or your representative files the signed form with us at one of our offices if you have initially filed a claim or have requested reconsideration; with the hearing office if you have requested a hearing; or with the Appeals Council if you have requested a review of the administrative law judge's decision.

(2) If your representative is a professional representative, or if your representative is not a professional representative but wants to do business with us through the electronic media we prescribe, we will recognize your appointment of a representative if—

(i) Your representative electronically signs the form we prescribe, prints the electronically signed form, and you sign the printed copy of the form;

(ii) You choose a principal representative on the form we prescribe at the time of the appointment; and

(iii) Your representative files the electronic form in the manner we prescribe.

(3) If we do not make the electronic form available or we prescribe that the electronic form is not required, then we will recognize your appointment of a professional representative according to the procedures in paragraph (a)(1) of this section.

(b) Each time you change your principal representative, you must file a new version of the form we prescribe.

(c) If at any point you are represented by more than one representative and you have not appointed or do not have a principal representative, we will name one of your appointed representatives as your principal representative. You may appoint a different principal representative than the one we name by filing the appropriate form.

(d) You must file the form we prescribe with us to revoke the appointment of a representative. The date of the revocation is the date on which you file the form with us. We will notify you and your representative that you revoked your representative's appointment.

47. Amend § 416.1510 by revising paragraphs (a) introductory text and (b) and by adding paragraph (c) to read as follows:

§ 416.1510 Authority of a representative.

(a) Your representative may, on your behalf—

* * * * *

(b) Your principal representative may also sign and file an application on your behalf for rights or benefits under title XVI of the Act, as described in § 416.315(d).

(c) If you appoint an entity as your representative, any document related to the claim that is signed by a registered employee of the entity is binding on that entity, even if the employee's association with the entity ends.

48. Add a new § 416.1512 to read as follows:

§ 416.1512 When the appointment of your representative begins and ends.

(a) The appointment of your representative begins on the date that you and your representative sign the form we prescribe appointing your representative as described in § 416.1507. However, we will not recognize your appointment of a representative or deal with your representative until you or your representative file(s) the signed form with us.

(b) If your appointed representative is an individual, the individual's authority continues until the earliest of the following actions occur—

(1) You file the prescribed form with us revoking the appointment of your representative;

(2) Your representative files the prescribed form with us withdrawing as your representative;

(3) We have made a final determination or decision on your claim of the period in which you or your representative could appeal our determination or decision has ended, and you or your representative did not file an appeal before the end of that period;

(4) Your representative files a fee petition requesting our authorization to charge and collect a fee (see §§ 416.1520 and 416.1525);

(5) We have closed out any application that was started by you or on your behalf but was not pursued within the time period we prescribe;

(6) We disqualify or suspend your representative; or

(7) Your representative dies.

(c) If your appointed representative is an entity, the entity's authority continues until the earliest of the following actions occur—

(1) You file the prescribed form with us revoking the appointment of your representative;

(2) Your representative files the prescribed form with us withdrawing as your representative.

(3) We have made a final determination or decision on your claim of the period in which you or your representative could appeal our determination or decision has ended, and you or your representative did not file an appeal before the end of that period;

(4) Your representative files a fee petition requesting our authorization to charge and collect a fee (see §§ 416.1520 and 416.1525);

(5) We have closed out any application that was started by you or on your behalf but was not pursued within the time period we prescribe;

(6) We disqualify or suspend your representative;

(7) The entity goes out of business; or

(8) The entity changes ownership or changes the services it provides, such that it no longer represents claimants before us.

(d) You may reappoint a representative by properly filing a new prescribed form with us in accordance with §§ 416.1505 and 416.1507.

49. Add a new § 416.1513 to read as follows:

§ 416.1513 Professional representatives.

(a) Professional representatives must conduct business with us electronically at the times and in the manner that we prescribe.

(b) Professional representatives, and individuals working on behalf of professional representatives on claims before us, must make certain attestations we require to ensure that each individual knows, understands, and will comply with our rules and regulations. Each of these individuals will make these attestations one time during the access registration process.

50. Revise § 416.1515 to read as follows:

§ 416.1515 Notice or request to a representative.

(a) We will send to you, your principal representative, and your other representatives, if any, all notices relating to the appointment of any of your representatives and the revocation or withdrawal of an appointment of any of your representatives. Notices sent in accordance with § 416.1530(c)(2)(i) will

be sent to any representative who has not filed a written request for a fee in accordance with § 416.1530(c)(1).

(b) We will send only to your principal representative—

(1) Notices and copies of any administrative action, determination, or decision in your claim; and

(2) Requests for information or evidence in your claim.

(c) If your principal representative is an entity, we will send all notices, copies of any administrative action, determination, or decision in your claim, and requests for information to the individual who signed the appointment of representative form on behalf of the entity, until or unless the entity informs us of a different contact within the entity for this purpose.

(d) Your principal representative is responsible for informing other appointed representatives, if any, about any notices, administrative actions, determinations, decisions, or requests for information or evidence that we send to the principal representative. We will not send copies of notices, any administrative actions, determinations, decisions, or requests for information or evidence to any representative, except your principal representative.

(e) Any notice or request we send to your principal representative will have the same force and effect as if we sent it directly to you.

51. Amend § 416.1520 by revising paragraphs (a), (b)(1), (b)(3), (b)(4), (c) introductory text, (c)(3) introductory text, the first two sentences of paragraph (d)(1), and the first sentence of paragraph (d)(2)(i) to read as follows:

§ 416.1520 Fee for a representative's services.

(a) *General.* A representative may charge and receive a fee for providing you with services as a representative as provided in paragraph (b) of this section or as provided in sections 206(a)(2) and 1631(d)(2) of the Act.

(b) *Charging and receiving a fee under the fee petition process.* (1) The representative must file a written fee petition with us before the representative may charge or receive a fee for providing you with services.

* * * * *

(3) A representative must not charge or receive any fee unless we have approved it, and a representative must not charge or receive any fee that is more than the amount we approve.

(4) If the representative is an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 416.1517, or an entity that meets the requirements in § 416.1530(f) and the claimant is entitled to past-due benefits, we will pay the authorized fee, or a part of the authorized fee, directly to the attorney, eligible non-attorney, or eligible entity out of the past-due benefits, subject to the limitations described in § 416.1530(b)(1). If the representative is not an attorney, eligible non-attorney, or eligible entity, we assume no responsibility for the payment of any fee that we have authorized.

(c) *Notice of determination on the fee petition.* We will mail to both you and your representative at your last known addresses a written notice of what we decide about the fee petition. We will state in the notice—

* * * * *

(3) That we are not responsible for paying the fee, except when we may pay an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 416.1517, or an entity that meets the requirements in § 416.1530(f), from past-due benefits; and—

* * * * *

(d) *Review of fee petition determination*-(1) *Request filed on time.* We will review the decision we made about a fee petition if either you or your representative files a written request for the review through the electronic media we prescribe or at one of our offices within 30 days after the date of the notice of the fee determination. Either you or your representative, whoever requests the review, must mail a copy of the request to the other person. * * *

(2) *Request not filed on time.* (i) If you or your representative requests a review of the decision we made about a fee, but does so more than 30 days after the date of the notice of the fee determination, whoever makes the request must state in writing why it was not filed within the 30-day period. * * *

* * * * *

52. Amend § 416.1525 by revising the section heading, paragraphs (a) introductory text, (a)(2) through (a)(6), the heading for paragraph (b), and paragraph (b)(1)(vii) to read as follows:

§ 416.1525 Request for approval of a fee petition.

(a) *Filing a written fee petition.* Unless your representative's fee is approved pursuant to sections 206(a)(2) and 1631(d)(2) of the Act, in order for your representative to obtain approval of a fee for services your representative performed in dealings with us, your representative must file a written fee petition through the electronic media we prescribe or at one of our offices. This should be done after the proceedings in which your representative represented you are completed. The request must contain—

* * * * *

(2) A list of the services your representative provided and the amount of time your representative spent on each type of service;

(3) The amount of the fee your representative wants to charge for the services;

(4) The amount of fee your representative wants to request or charge for representing you in the same matter before any State or Federal court;

(5) The amount of and a list of any expenses your representative incurred for which your representative has been paid or expects to be paid;

(6) A description of the special qualifications which enabled your representative, if not an attorney, to give valuable help in connection with your claim; and

* * * * *

(b) *Evaluating a request for approval of a fee petition.*

(1) * * *

(vii) The amount of fee the representative requests for the representative's services, including any amount authorized or requested before, but not including the amount of any expenses the representative incurred.

* * * * *

53. Amend § 416.1528 by revising paragraph (a) to read as follows:

§ 416.1528 Proceedings before a State or Federal court.

(a) *Representation of a party in court proceedings in fee petitions.* We will not consider any service the representative gave you in any proceeding before a State or Federal court to be services as a representative in dealings with us. However, if the representative also has given service to you in the same connection in any dealings with us, the representative must specify what, if any, portion of the fee the representative wants to charge is for services performed in dealings with us. If the representative charges any fee for those services, the representative must file the request and furnish all of the information required by § 416.1525.

* * * * *

54. Revise § 416.1530 to read as follows:

§ 416.1530 Payment of fees.

(a) *Fees allowed by a Federal court in fee petitions.* We will pay a representative who is an attorney out of your past-due benefits, the amount of the fee allowed by a Federal court in a proceeding under title XVI of the Act.

This payment is subject to the limitations described in paragraph (b)(1) of this section.

(b) *Fees we may authorize for payment in fee petitions*—(1) *Attorneys, eligible non-attorneys, and eligible entities.* Except as provided in paragraphs (c) and (f) of this section, if we make a determination or decision in your favor and you were represented by an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 416.1517, or an entity that meets the requirements in paragraph (g) of this section, and as a result of the determination or decision you have past-due benefits, we will pay the representative out of the past-due benefits, the smallest of the amounts in paragraphs (b)(1)(i) through (iii) of this section, less the amount of the assessment described in paragraph (d) of this section.

(i) Twenty-five percent of the total of the past-due benefits, as determined before any payment to a State (or political subdivision) to reimburse the State (or political subdivision) for interim assistance furnished you, as described in § 416.525, and reduced by the amount of any reduction in benefits under this title or title II pursuant to section 1127 of the Act;

(ii) The amount of past-due benefits remaining after we pay to a State (or political subdivision) an amount sufficient to reimburse the State (or political subdivision) for interim assistance furnished you, as described in § 416.525, and after any applicable reductions under section 1127 of the Act; or

(iii) The amount of the fee that we set.

(2) *Persons not eligible for direct payment.* If the representative is a non-attorney who is not eligible to participate in the direct payment demonstration project or an entity that is not eligible for direct payment of the fee, we assume no responsibility for the payment of any fee that we have authorized. We will not deduct the fee your past-due benefits.

(c) *Time limit for filing request for approval of fee petition to obtain direct payment.* (1) To receive direct payment of a fee from your past-due benefits, a representative who is an attorney, a non-attorney who is eligible to participate in the direct payment demonstration project, as defined in § 416.1517, or an entity that meets the requirements in paragraph (g) of this section should file a request for approval of a fee or a written notice of the intent to file a request within 60 days of the date we mail the notice of the favorable determination or decision. The representative should file the request or written notice through the electronic media we prescribe or at one of our offices. Your representative must send you a copy of any request for approval of a fee, any written notice of the intent to file a request for approval of a fee, or any request for an extension of time filed with us.

(2)(i) If no request is filed within 60 days of the date we mail the notice of the favorable determination or decision, we will mail a written notice to you and your representative at your last known addresses. The notice will inform you and the representative that unless the representative files, within 20 days from the date of the notice, a written request for approval of a fee under § 416.1525, or a written request for an extension of time showing good cause (see § 416.1411), we will pay all the past-due benefits to you.

(ii) Your representative must send you a copy of any request made to us for an extension of time. If the request is not filed within 20 days of the date of the notice we send under paragraph (c)(2)(i) of this section, or by the last day of any extension we approved, we will pay all past-due benefits to you. We must approve any fee your representative charges after that time, but the collection of any approved fee is a matter between you and your representative.

(d) *Assessment when we pay a fee directly to a representative.* (1) Whenever we pay a fee directly to a representative from past-due benefits, we impose an assessment on the representative.

(2) The amount of the assessment is equal to the lesser of:

(i) The product we obtain by multiplying the amount of the fee we are paying to the representative by the percentage rate the Commissioner of Social Security determines is necessary to achieve full recovery of the costs of determining and paying fees directly to representatives, but not in excess of 6.3 percent; and

(ii) The maximum assessment amount. The maximum assessment amount was initially set at $75, but by law is adjusted annually to reflect the increase in the cost-of-living. (See §§ 404.270 through 404.277 for an explanation of how the cost-of-living adjustment is computed.) If the adjusted amount is not a multiple of $1, we round down the amount to the next lower $1, but the amount will not be less than $75. We will announce in the **Federal Register** any increase in the maximum assessment amount and explain how that increase was determined.

(3) We collect the assessment by subtracting it from the amount of the fee to be paid to the representative. The representative who is subject to an assessment may not, directly or indirectly, request or otherwise obtain reimbursement of the assessment from you.

(e) *Effective dates for extension of direct payment of fee to attorneys.* The provisions of this subpart authorizing the direct payment of fees to attorneys and the withholding of title XVI benefits for that purpose, apply in claims for benefits with respect to which the agreement for representation is entered into before March 1, 2010.

(f) *Direct payment registration.* (1) To receive direct payment, the representative must first complete direct payment registration with us in the form and manner that we prescribe.

(2) We will only make direct payment of fees via electronic funds transfer.

(g) *Direct payment to entities.* We will only make direct payment to an entity that provides the following attestations in its request for direct payment of fees:

(1) The entity must attest that it is in possession of a signed statement from each attorney or non-attorney who has performed any representational services for the claim in question that includes the following:

(i) The attorney or non-attorney has performed all representational services on behalf of the entity,

(ii) Any fees paid pursuant to the services the attorney or non-attorney have provided should be paid directly to the entity, and

(iii) The attorney or non-attorney representative receives compensation for the services provided directly from the entity.

(2) The entity must attest that all individuals who have provided representational services on the claim in question are individuals who qualify for direct payment under the Act or the direct payment demonstration project, as defined in § 416.1517.

55. Add a new § 416.1532 to read as follows:

§ 416.1532 Waiver of fee or direct payment, or both.

(a) Your representative may choose to waive the right to charge and receive a fee. An otherwise eligible representative who wishes to charge and receive a fee may waive the right to direct payment. A representative who waives the right to direct payment does not automatically waive the right to charge and receive a fee.

(b) Your representative must file a form we prescribe to waive direct payment of the fee.

(c) A waiver of the right to charge and receive a fee or of direct payment, or both, will apply to fees approved by a Federal court, unless it is otherwise specifically noted on the form completed in accordance with paragraph (b) of this section.

(d) If you have appointed an entity as your representative, any registered employee of the entity may sign the form completed in accordance with paragraph (b) of this section to waive the fee or direct payment, or both, on behalf of the entity.

56. Amend § 416.1540 by revising the first sentence of paragraph (a)(1), paragraph (b) introductory text, paragraph (b)(3) introductory text, the third sentence of paragraph (b)(3)(i), and the second sentence of paragraph (b)(3)(ii), adding paragraphs (b)(3)(iii) and (b)(4), revising paragraphs (c) introductory text , (c)(4), (c)(6), and (c)(7)(iii), and adding paragraphs (c)(8) through (c)(13) to read as follows:

§ 416.1540 Rules of conduct and standards of responsibility for representatives.

(a) * * * (1) All persons acting on behalf of a party seeking a statutory right or benefit must, in their dealings with us, faithfully execute their duties as agents and fiduciaries of a party.

* * *

(b) *Affirmative duties.* A representative must, in conformity with the regulations setting forth our existing duties and responsibilities and those of claimants (see § 416.912 in disability and blindness claims):

* * * * *

(3) Conduct the representative's dealings in a manner that furthers the efficient, fair, and orderly conduct of the administrative decision-making process, including duties to:

(i) * * * This includes knowing the significant issue(s) in a claim and having a working knowledge of the applicable provisions of the Social Security Act, as amended, the regulations and the Rulings;

(ii) * * * This includes providing prompt and responsive answers to requests from the Agency for information pertinent to processing of the claim; and

(iii) Maintain a paper copy of the form described in § 416.1507(a) that reflects the representative's and the claimant's signatures and respective signature dates appointing the representative, and maintain copies of the signed attestations described in § 416.1530(g), and provide paper copies to us on request.

(4) If the representative is a professional representative, conduct business with us electronically at the times and in the manner that we prescribe when submitting any written request for reconsideration or a hearing before an administrative law judge on an initial disability claim that was based on medical factors.

(c) *Prohibited actions.* A representative must not:

* * * * *

(4) Through the representative's own actions or omissions, unreasonably delay or cause to be delayed, without good cause (see § 416.1411(b)), the processing of a claim at any stage of the administrative decision-making process;

* * * * *

(6) Attempt to influence, directly or indirectly, the outcome of a decision, determination or other administrative action by offering or granting a loan, gift, entertainment or anything of value to a presiding official, Agency employee or witness who is or may reasonably be expected to be involved in the administrative decisionmaking process, except as reimbursement for legitimately incurred expenses or lawful compensation for the services of an expert witness retained on a non-contingency basis to provide evidence;

(7) * * *

(iii) Threatening or intimidating language, gestures or actions directed at a presiding official, witness or Agency employee which results in a disruption of the orderly presentation and reception of evidence;

(8) Violate any section of the Social Security Act for which a criminal or civil monetary penalty is prescribed;

(9) Refuse to comply with any of our rules or regulations;

(10) Suggest, assist, or direct another person to violate our rules or regulations;

(11) Advise any claimant or beneficiary not to comply with any of our rules and regulations;

(12) Assist another person whom we have suspended or disqualified; or

(13) Fail to comply with our decision regarding sanctions.

57. Amend § 416.1550 by revising paragraphs (a) and (d) to read as follows:

§ 416.1550 Notice of charges against a representative.

(a) The General Counsel (or other official the Commissioner may designate), or his or her designee, will prepare a notice containing a statement of charges that constitutes the basis for the proceeding against the representative.

* * * * *

(d) The General Counsel (or other official the Commissioner may designate), or his or her designee, may extend the 30-day period for good cause in accordance with § 416.1411.

* * * * *

58. Revise § 416.1555 to read as follows:

§ 416.1555 Withdrawing charges against a representative.

The General Counsel (or other official the Commissioner may designate), or his or her designee, may withdraw charges against a representative. We will do this if the representative files an answer, or we obtain evidence, that satisfies us that we should not suspend or disqualify the representative from acting as a representative in dealings with us. When we consider withdrawing charges brought under § 416.1545(d) or (e) based on the representative's assertion that, before or after our filing of charges, the representative has been reinstated to practice by the court, bar, or Federal program or Federal agency that suspended, disbarred, or disqualified the representative, the General Counsel (or other official the Commissioner may designate), or his or her designee, will determine whether such reinstatement occurred, whether it remains in effect, and whether he or she is reasonably satisfied that the representative will in the future act in accordance with the provisions of section 206(a) of the Act and our rules and regulations. If the representative proves that reinstatement occurred and remains in effect and the General Counsel, or his or her designee, is so satisfied, the General Counsel, or his or her designee, will withdraw those charges. The action of the General Counsel, or his or her designee, regarding withdrawal of charges is solely that of the General Counsel (or other official the Commissioner may designate), or his or her designee, and is not reviewable, or subject to consideration in decisions made under §§ 416.1570 and 416.1590. If we withdraw the charges, we will notify the representative by mail at the representative's last known address.

59. Amend § 416.1565 by revising paragraphs (a), (b)(1), and (e), the first sentence of paragraph (g)(2), and paragraphs (i), (l), and (m) to read as follows:

§ 416.1565 Hearing on charges.

(a) *Holding the hearing.* If the General Counsel (or other official the Commissioner may designate), or his or her designee, does not take action to withdraw the charges within 15 days after the date on which the representative filed an answer, we will hold a hearing and make a decision on the charges.

(b) *Hearing officer.* (1) The Deputy Commissioner for Disability Adjudication and Review (or other official the Commissioner may designate), or his or her designee, will assign an administrative law judge, designated to act as a hearing officer, to hold a hearing on the charges.

* * * * *

(e) *Parties.* The representative against whom charges have been made is a party to the hearing. The General Counsel (or other official the Commissioner may designate), or his or her designee, will also be a party to the hearing.

* * * * *

(g) Conduct of the hearing. * * *

(2) If the representative did not file an answer to the charges, the representative has no right to present evidence at the hearing. * * *

* * * * *

(i) *Witnesses.* Witnesses who testify at the hearing must do so under oath or affirmation. Either the representative or a person representing the representative may question the witnesses. The other party and that party's representative must also be allowed to question the witnesses. The hearing officer may also ask questions as considered necessary, and will rule upon any objection made by either party about whether any question is proper.

* * * * *

(l) *Representation.* The representative, as the person charged, may appear in person and may be represented by an attorney or other representative. The General Counsel (or other official the Commissioner may designate), or his or her designee, will be represented by one or more attorneys from the Office of the General Counsel.

(m) *Failure to Appear.* If the representative or the other party to the hearing fails to appear after being notified of the time and place, the hearing officer may hold the hearing anyway so that the party present may offer evidence to sustain or rebut the charges. The hearing officer will give the other party who failed to appear an opportunity to show good cause for failure to appear. If the party fails to show good cause, the party is considered to have waived the right to be present at the hearing. If the party shows good cause, the hearing officer may hold a supplemental hearing.

* * * * *

60. Amend § 416.1570 by revising paragraphs (a)(1), (a)(2), (a)(3) introductory text, (a)(3)(ii), (b)(2), and (b)(3) to read as follows:

§ 416.1570 Decision by hearing officer.

(a) *General.* (1) After the close of the hearing, the hearing officer will issue a decision or certify the case to the Appeals Council. The decision must be in writing, will contain findings of fact and conclusions of law, and be based upon the evidence of record.

(2) In deciding whether a person has been, by reason of misconduct, disbarred or suspended by a court or bar, or disqualified from participating in or appearing before any Federal program or agency, the hearing officer will consider the reasons for the disbarment, suspension, or disqualification action. If the action was taken for solely administrative reasons (e.g., failure to pay dues or to complete continuing legal education requirements), that will not disqualify the person from acting as a representative before us. However, this exception to disqualification does not apply if the administrative action was taken in lieu of disciplinary proceedings (e.g., acceptance of a voluntary resignation pending disciplinary action). Although the hearing officer will consider whether the disbarment, suspension, or disqualification action is based on misconduct when deciding whether a person should be disqualified from acting as a representative before us, the hearing officer will not re-examine or revise the factual or legal conclusions that led to the disbarment, suspension, or disqualification.

(3) If the hearing officer finds that the charges against the representative have been sustained, he or she will either—

* * * * *

(ii) Disqualify the representative from acting as a representative in dealings with us until the representative may be reinstated under § 416.1599. Disqualification is the sole sanction available if the charges have been sustained because the representative has been disbarred or suspended from any court or bar to which the representative was previously admitted to practice or disqualified from participating in or appearing before any Federal program or agency, or because the representative has collected or received, and retains, a fee for representational services in excess of the amount authorized.

* * * * *

(b) *Effect of hearing officer's decision.* * * *

(2) If the final decision is that a person is disqualified from being a representative in dealings with us, the representative will not be permitted to represent anyone in dealings with us until authorized to do so under the provisions of § 416.1599.

(3) If the final decision is that a person is suspended for a specified period of time from being a representative in dealings with us, the representative will not be permitted to represent anyone in dealings with us during the period of suspension unless authorized to do so under the provisions of § 416.1599.

61. Amend § 416.1580 by revising paragraph (b) to read as follows:

§ 416.1580 Appeals Council's review of hearing officer's decision.

* * * * *

(b) If a party files a brief or other written statement with the Appeals Council, the party must send a copy to the opposing party and certify that the copy has been sent.

62. Amend § 416.1599 by revising paragraphs (b), (c), (d)(2), (d)(3), and (e), to read as follows:

§ 416.1599 Reinstatement after suspension or disqualification—period of suspension not expired.

* * * * *

(b) The suspended or disqualified person must submit any evidence the person wishes to have considered along with the request to be allowed to serve as a representative again.

(c) The General Counsel (or other official the Commissioner may designate), or his or her designee, upon notification of receipt of the request, will have 30 days in which to present a written report of any experiences with the suspended or disqualified person subsequent to that person's suspension or disqualification. The Appeals Council will make available to the suspended or disqualified person a copy of the report.

(d) * * *

(2) If a person was disqualified because the person had been disbarred or suspended from a court or bar, the Appeals Council will grant a request for reinstatement as a representative only if the criterion in paragraph (d)(1) of this section is met and the disqualified person shows that the person has been admitted (or readmitted) to and is in good standing with the court or bar from which the person had been disbarred or suspended.

(3) If a person was disqualified because the person had been disqualified from participating in or appearing before a Federal program or Federal agency, the Appeals Council will grant the request for reinstatement only if the criterion in paragraph (d)(1) of this section is met and the disqualified person shows that the person is now qualified to participate in

or appear before that Federal program or Federal agency.

* * * * *

(e) The Appeals Council will mail a notice of its decision on the request for reinstatement to the suspended or disqualified person. It will also mail a copy to the General Counsel (or other official the Commissioner may designate), or his or her designee.

* * * * *

PART 422—ORGANIZATION AND PROCEDURES

Subpart C—[Amended]

63. The authority for subpart C of part 422 continues to read as follows:

Authority: Secs. 205, 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 421, and 902(a)(5)); 30 U.S.C. 923(b).

64. Amend § 422.203 by revising paragraph (b)(1) to read as follows:

§ 422.203 Hearings.

* * * * *

(b) *Request for hearing.* (1) A request for a hearing under paragraph (a) of this section may be made on Form HA–501, ''Request for Hearing,'' Form HA–501.1, ''Request for Hearing, part A Hospital Insurance Benefits,'' electronically at the times and in the manner that we prescribe (see §§ 404.933, 404.934, 416.1433, and 416.1434 of this chapter), or by any other writing requesting a hearing. The request must be filed at an office of the Social Security Administration, usually a district office or a branch office, or at the Veterans Administration Regional Office in the Philippines (except in title XVI cases), or at a hearing office of the Office of Disability Adjudication and Review, or with the Appeals Council. A qualified railroad retirement beneficiary may, if (s)he prefers, file a request for a hearing under part A of title XVIII with the Railroad Retirement Board. Form HA–501 may be obtained from any Social Security district office or branch office.

* * * * *

Subpart F—[Amended]

65. The authority citation for subpart F of part 422 continues to read as follows:

Authority: Sec. 1140(a)(2)(A) of the Social Security Act. 42 U.S.C. 1320b–10(a)(2)(A) (Pub. L. 103–296, Sec. 312(a)).

66. Amend § 422.515 by adding a second sentence to the introductory text to read as follows:

§ 422.515 Forms used for withdrawal, reconsideration and other appeals, and appointment of representative.

* * * Prescribed forms include our traditional pre-printed forms, forms completed on computer screens based on information you give us, or SSA-approved forms completed and submitted using SSA's Internet Web site.

* * * * *

[FR Doc. E8–20500 Filed 9–5–08; 8:45 am]

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POSTAL REGULATORY COMMISSION

39 CFR Part 3001

[Docket No. RM2008–2; Order Nos. 99 and 102]

Periodic Reporting Rules

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rule; availability of rulemaking petition.

SUMMARY: Under a new law, the Postal Service must file an annual compliance report with the Postal Regulatory Commission on costs, revenues, rates, and quality of service associated with its products. It has filed documents with the Commission to change some of the methods it uses to compile the fiscal year 2008 report. In the Commission's view, these documents constitute a rulemaking petition. Therefore, it has established a rulemaking docket to allow the public to comment on potential changes in periodic reporting rules.

DATES: 1. Technical conference: August 27, 2008 at 10 a.m.

2. Initial comments: September 8, 2008.

3. Reply comments: September 15, 2008.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 and *stephen.sharfman@prc.gov*.

SUPPLEMENTARY INFORMATION: On August 11, 2008, the Commission received Request of the United States Postal Service for Commission Order Amending the Established Costing Methodologies for Purposes of Preparing the FY 2008 Annual Compliance Report (Request). In the Request, the Postal Service states that it has eight changes that it would like to make to the methods by which it compiles the FY 2008 version of the annual report that is required by 39 U.S.C. 3652 to provide to the Commission each year. It cites 39 U.S.C. 3652(a)(1), which gives the Commission the responsibility to prescribe methods that are used to produce the information that is compiled in the annual report. Request at 2. Among other things, the information supplied in the annual report is used by the Commission to prepare the Annual Compliance Determination (ACD) that is required by 39 U.S.C. 3653.

The Postal Service references pages 9–10 of the most recent Commission ACD. FY 2008 Annual Compliance Determination, March 27, 2007 (FY 2007 ACD). There, numerous commenters recommended that the Postal Service not change methods for collecting and analyzing cost data unless interested persons have had an opportunity to evaluate and comment on them. The Commission concurred, stating that it intended to issue regulations governing periodic reports generally (including the Postal Service's annual report) that would vet proposed changes in analytical methods through informal rulemakings in advance of the filing of the report. FY 2007 ACD at 10.

I. Procedural Expedition

The Postal Service notes that it is already preparing its annual report for FY 2008. Given the lead time that is required, it observes that it is unlikely that the regulations that the Commission described in its FY 2007 ACD can be issued, and public scrutiny of particular changes in analytical methods could be completed under those regulations, in time to be incorporated in its FY 2008 annual report. It therefore asks that an alternative, expedited procedure be used to vet its proposed changes in analytical methods.

In the Postal Service's view, none of its proposed methodological changes ''are of sufficient complexity to hinder relatively straightforward evaluation by both the parties and the Commission.'' Request at 2. It therefore proposes that its filing be treated as a rule 21 motion for a Commission order approving its proposed changes to current baseline methods used to analyze costs. *Id.,* n.2. The Postal Service notes that its Request includes the rationale for each of the eight methodological changes that it proposes, and estimates the impact of each change on the costs borne by mail classes. Equipped with this information, it suggests, the public could provide input in the form of answers supporting or opposing the motion. It recognizes, however, that the 7-day period that rule 21 allows for answers to motions should

probably be lengthened. The Postal Service notes that if interested parties feel that more elaborate procedures for their input are needed, they can include those suggestions in their answers. *Id.* at 2. As noted, the Postal Service's petition is followed by a description of each proposal, together with its background, objective, and supporting rationale.[1]

Although it does not have all of the changes to baseline analytical methods that it hopes to incorporate in its 2008 annual report ready to submit for public comment, the Postal Service observes that the process should begin. It notes that these proposed changes would be part of the core cost and revenue analysis process, which must be finalized before other changes, such as those from new special studies, can be added to its cost and revenue analysis. It says that other proposed changes will be submitted for public scrutiny as they are developed. *Id.* at 3.

The Commission agrees that the process of vetting proposed changes in the methods by which cost incurrence will be analyzed in the Postal Service's FY 2008 annual report should begin now with those proposals that are sufficiently refined to be submitted for public comment. The Request suggests that it should be procedurally sufficient for the Commission to adopt an order ruling on its proposed methodological changes. The Commission, however, prefers at least initially to interpret the definition of a ''rule'' in the Administrative Procedure Act (APA) to include analytical methods that affect the way costs or revenues are accounted for in a rate setting regulatory regime. The APA requires that notice be given in the **Federal Register** and an opportunity for public comment be provided before substantive rules take effect. *See* 5 U.S.C. 551(4) and 553. For this reason, the Commission will treat the Postal Service's August 11, 2008 filing as a petition to initiate an informal rulemaking consistent with section 553 of the APA.

The Commission hereby grants the Postal Service's petition. Since time is of the essence in vetting these proposed methodological changes, the Commission is tentatively scheduling a technical conference in which Postal Service experts would be available to answer questions related to these proposals. The technical conference will be held on August 27, 2008 at 10 a.m. in the Commission's hearing room. The Postal Service should also arrange for the possibility that a follow-up technical conference could be held on the afternoon of September 3, 2008, if needed. Interested persons may file written comments on the Postal Service's proposals on or before September 8, 2008. Reply Comments may be filed on or before September 15, 2008.

II. Substance of Postal Service Proposals

The Postal Service proposals, *see* Request at 5 *et seq.,* are described below.

Proposal One. Proposed Group Specific Cost Change (Cost Segment 18).

Objective: A methodology change is proposed for the manner in which headquarters Finance Number (FN) Cost Segment 18 costs are categorized in the FY 2008 Cost & Revenue Analysis (CRA) Report.

Background: In FY 2007, and for years before, almost all Cost Segment 18 costs for headquarters Finance Numbers were treated as institutional costs. With the enactment of the Postal Act of 2006, however, there is a need to define a new category of cost—''group-specific'' cost. Group-specific costs are those costs which cannot be attributed to individual products, but which are caused by either the competitive or market-dominant products as a group. The remaining business sustaining or common fixed costs are ''institutional.'' An example of a competitive product group-specific cost would be a HQ organization unit that only supports competitive products. Pursuant to Commission rule 3015.7(a), the Commission is currently using competitive products' attributable costs, supplemented to include causally related, group-specific costs, to test for cross-subsidies.

Competitive products also must cover an ''appropriate share'' of institutional cost. In addition to the identification of competitive product group-specific costs, the identification of market-dominant group-specific costs is also important, as the value of the institutional cost will be the residual of postal costs that are not attributable to products and are not group-specific to either group. To the extent costs are group-specific costs, the remaining ''institutional cost'' will be a smaller amount than it would be otherwise.

Proposal: The new taxonomy for costs places a new requirement to be able to identify group-specific HQ administrative and program costs for market-dominant and competitive product groups. The Postal Service captures costs for administrative activities and programs using a cost center designation of the ''Finance Number.'' Administrative organization units and programs are assigned a Finance Number and all expenses are charged to the Finance Number. Most Headquarters activities and programs support the entire enterprise or support all products. However, the cost in some Finance Numbers may be associated with either competitive or market-dominant product groups.

To facilitate the identification of group-specific costs in Headquarters, the Postal Service has created a new attribute for Finance Numbers called the Product Activity Attribute. The value of the Product Activity Attribute will indicate which of the following describes the activities and costs of the Headquarters Finance Number:

Market-Dominant—Activity in Finance Number only supports Market-Dominant Products.

Competitive—Activity in Finance Number only supports Competitive Products.

Common/Enterprise Sustaining—Activity in Finance Number supports both groups of products, or supports the Enterprise as a whole.

In the analysis to support the Annual Compliance Report beginning in FY 2008, the Postal Service proposes to use the value of the Product Activity Attribute for Headquarters Finance Numbers to help identify group-specific costs (and possibly some product-specific costs) for competitive and market-dominant products. That is, expenses in Finance Numbers deemed ''Market-Dominant'' would be candidates for market-dominant group-specific costs and expenses in Finance Numbers deemed ''Competitive'' would be candidates for competitive product group-specific costs. Costs in Finance Numbers deemed ''Common/Enterprise Sustaining'' would be candidates for Institutional Cost. The analysis of group-specific costs by Finance Number would not replace, but rather would supplement, existing volume-variable and product-specific analysis of expenses in Headquarters Finance Numbers.

[1] Time Warner Inc. (Time Warner) has responded with a motion asking that the deadline for answers be extended to September 2, 2008. *See* Motion of Time Warner Inc. to Extend the Period for Response to Request of the United States Postal Service for Commission Order Amending the Established Costing Methodologies for Purposes of Preparing the FY 2008 Annual Compliance Report, August 14, 2008 (Motion). It argues that the substance of these proposals is not sufficiently simple and straightforward to be vetted in 7 days. It argues, further, that it needs more time to examine and comment on the alternative procedures that the Postal Service proposes, particularly if they are to become standard procedures for vetting methodological changes. Motion at 3–4. The rulemaking procedures and extended deadlines authorized in this notice should meet Time Warner's procedural objections.

Approach To Determine Value of the Product Activity Attribute

A. Existing Finance Numbers

The Postal Service is conducting a survey of the owners of the Headquarters Finance numbers to obtain information on the type of activity or program performed in the Finance Number. Responses to the survey will be used to help ascertain whether the activity supports a specific product group or is Common/Enterprise Sustaining. The Cost Attribution unit in Corporate Financial Planning will analyze the results of the survey and conduct further research as necessary to determine the appropriate value of the Product Activity Attribute for each Finance Number. The value of the Product Activity Attribute will be populated in the Finance Number Control Master File.

B. New Finance Numbers

The Postal Service will modify its current business process for the creation of new Finance Numbers to include a step for the requestor of the new Finance Number to respond to the Product Activity Survey Questions. The Cost Attribution unit in Corporate Financial Planning will serve as the gate-keeper for review and approval of the value of the Product Activity Attribute in the official Finance Number Control Master File.

Impact: The proposed approach is designed to position the Postal Service to identify group-specific costs as the organization and strategies for Mailing Services (*i.e.*, Market-dominant products) and Shipping Services (*i.e.*, Competitive products) evolve. The Postal Service does not have survey data to estimate the impact of the proposed approach on FY 2007 costs and, because of the substantial amount of HQ organizational restructuring which has taken place this fiscal year, believes that historical information from FY 2007 would have limited value in projecting future group-specific costs. The typical FN at headquarters usually contains several million dollars, however, so depending on the numbers of FNs determined to be Market-Dominant or Competitive Product, something between tens of millions to perhaps as much as several hundreds of millions of dollars would be expected to move out of institutional costs and into group specific costs.

Proposal Two: Proposed Group-Specific Cost Change (Cost Segment 16).

Objective: A methodology change is proposed for the manner in which advertising costs (Cost Segment 16) for Click-N-Ship and Carrier Pickup are assigned in the FY 2008 Cost & Revenue Analysis (CRA) Report.

Background: In the FY 2007 CRA, the advertising costs for Click-N-Ship and Carrier Pickup were treated as institutional, even though these costs related to specific products (Express Mail, Priority Mail, International packages, International Express Mail, and International Priority Mail), all of which are Competitive Products.

Proposal: In FY 2008, it is proposed that advertising costs for Click-N-Ship and Carrier pickup be assigned as a group-specific cost to competitive products, as the advertising for these services relates specifically to products that are competitive.

Impact: In FY 2007, approximately $40 million was spent on advertising for Click-N-Ship and Carrier Pickup, together. Therefore, a similar amount of group-specific costs to competitive products might be expected in FY 2008.

Proposal Three: Proposed In-Office Cost System (IOCS) Mixed Mail. Coding Changes. Objective: changes are proposed to the IOCS coding of mixed mail that better support shape-based costing by the Postal Service.

Background: Currently, readings observed on employees handling wheeled containers, pallets, and empty containers are assigned mixed mail activity codes that depend only on the operation where the sampled employee was assigned. While this approach works well for employees in operations that handle a single shape of mail, it is fairly imprecise for allied operations such as platform.

Proposal: For FY 2008, it is proposed to use additional information on the shape (letter, flat, or parcel) of the contents in a wheeled container or pallet when assigning IOCS mixed mail codes. If the contents are all of the same shape (for example, all loose letter-shaped mail and letter trays), it is proposed to assign the mixed mail code to the corresponding shape. For empty equipment, it is proposed to assign a shape-based mixed mail code that corresponds to the equipment type; for example, empty letter trays would be assigned a letter-shape code. Containers that contain multiple shapes or no shape information would continue to be assigned as they are now.

Impact: There would be a decrease in the IOCS dollar-weighted tallies associated with IOCS activity codes for mixed mail all shapes and empty equipment of approximately 28 percent, and a corresponding increase in shape-specific mixed mail codes of 86 percent. These changes, when incorporated in the mail processing model, would slightly increase unit costs for parcel-shape mail, slightly decrease them for letter-shape mail, and leave costs for flat-shape almost unchanged.

Proposal Four: Proposed City Carrier Collection Cost Change. Objective: A change is proposed to identify an additional $60 million of First-Class Mail product specific cost in collection costs for city delivery carriers.

Background: In the FY 2007 CRA, the Postal Service attributed the non-volume variable portion ($60 million) of the city carrier time, associated with picking up mail in blue collection boxes, to First-Class single-piece letters. However, in the Commission's FY 2007 Annual Compliance Determination Report, the Commission rejected this treatment.

Proposal: For FY 2008, the Postal Service again proposes that this $60 million be attributed to First-Class single-piece letters. These costs represent a portion of the labor costs for collecting mail at ''blue'' collection boxes. The Commission correctly noted in its FY 2007 Annual Compliance Determination that the boxes do not state that their use is solely for the collection of First-Class single-piece letters. Still, over 90 percent of collection box mail is First-Class single-piece letters. (Moreover, in the new regime, single-piece letters and single-piece cards are now both components of the same Mail Classification Schedule ''product'' to which these costs will be treated as product specific, which is a change from the old regime in which cards and letters were separate subclasses.) Collection boxes are put into service for collecting First-Class single-piece letters, though a small amount of other products are sometimes deposited there. Furthermore, as of July 2007, the Postal Service prohibited stamped mail over 13 ounces from being deposited in these collection boxes, for security reasons. This would exclude some classes of mail that would have been there previously. Finally, with Carrier Pickup, competitive products such as Express and Priority Mail now have an alternative to using collection boxes. Therefore, the non-volume variable labor costs of sweeping collection boxes are reasonably treated as product specific to First-Class single-piece letters. Of course, to the limited extent that other types of mail are deposited in collection boxes, they will continue to get a proportionate distribution of the volume-variable costs, based on the existing distribution key.

Impact: The impact is $60 million of attributable cost for First-Class single-piece letters, which would be institutional otherwise.

Proposal Five: Proposed Express Mail Processing Changes. Objective: The purpose of this document is to propose addressing and implementing the changes recommended in the Commission's FY 2007 Annual Compliance Determination Report for (1) the distribution key for the costs of the mail processing activity called ''out of office, delivering Express Mail,'' and (2) the treatment of the non-volume variable portion of the cost for the same mail processing activity.

Background: In the FY 2007 CRA, the distribution key used for the costs of the mail processing activity called ''out of office, delivering Express Mail'' were the costs of the mail processing activities that the clerks were performing when they were ''in office.'' However, in the Commission's FY 2007 Annual Compliance Determination Report, the Commission suggested using Revenue, Pieces, and Weight (RPW) volumes of domestic and international Express to distribute the ''out of office, delivering Express Mail'' costs. Thus, the Postal Service is proposing adoption of the Commission's suggestion.

In the FY 2007 CRA, the non-volume variable portion (57 percent) of the costs for the ''out of office, delivering Express Mail'' activity was treated as institutional. In the Commission's FY 2007 Annual Compliance Determination Report, the Commission suggested the Postal Service review this variability/treatment and return with further suggestions.

Proposal: For FY 2008, the Postal Service proposes adopting the Commission's suggestion to use the relative RPW volumes of domestic and international Express Mail to form the distribution key.

For FY 2008, since the Postal Service does not have a new study to update the variability, it is proposing continuing with the 43 percent variability (with the remaining 57 percent non-volume variable), and also proposing to treat the 57 percent non-volume variable amount as group-specific to Competitive Products, as these costs are solely for domestic and international Express Mail, which are both Competitive Products.

Impact: Using the RPW volume of domestic and international Express Mail shifts about $4.346 million away from domestic Express Mail and into international Express Mail (using FY 2007 cost information in C/S 3.1 inputs to the spreadsheets).

Treating the 57 percent non-volume variable costs as Group Specific to Competitive Products shifts about $33.882 million from Institutional Costs to Attributable Competitive Group Specific (using FY 2007 cost information).

Proposal Six: Proposed Change to Distribution of Empty Equipment Costs

Objective: For FY 2008, the Postal Service proposes a change in the methodology by which attributable empty equipment Cost Segment 14 (Purchased Transportation) costs are distributed to products.

Background: Accrued purchased transportation empty equipment costs are contained in two general ledger accounts, 53191 and 53192, for highway and rail empty equipment costs, respectively. Empty equipment costs are generally incurred when empty equipment items, i.e. letter trays, flat tubs, sacks, rolling stock, etc., are transported between mail processing facilities and Mail Transport Equipment Service Centers (MTESC), or from MTESC directly to large mailers.

The attributable costs are computed by applying the variability factor to the accrued costs. The variability for transporting empty equipment by highway is the average cost weighted variability from all contracted highway transportation (approximately 80 percent). The variability for transporting empty equipment by rail is equal to the freight rail variability (approximately 99 percent). The Postal Service is not proposing any change in the variability factor applied to either highway or rail accrued empty equipment costs.

Currently, after the highway and rail attributable empty equipment costs are computed, they are distributed to products in the same proportions as the aggregate of all non-amphibious (that is, with the exception of inland and offshore water) Cost Segment 14 costs, using a simple three-step process. First, all other attributable Cost Segment 14 costs are distributed to products based on the distribution keys and distribution factors for the various other Cost Segment 14 components. Second, based on the results of the first step, the cumulative proportion of all non-amphibious Cost Segment 14 costs that have been distributed to each product is calculated. Third, each product then receives the same proportion of empty equipment costs as it received of total of all non-amphibious Cost Segment 14 costs. This methodology has been utilized in PRC versions of the CRA since FY 2000.

Proposal: In the second step of the distribution process described above, the Postal Service is proposing to exclude a portion of Cost Segment 14 costs mapped to component 828 (Total International) when calculating the cumulative distribution factors used to distribute highway and rail empty equipment attributable costs to products. Specifically, it proposes to exclude costs from accounts 53261, 53262, 53263, and 53268 before calculating the distribution key that attributes empty equipment costs to products. In FY07, those four accounts totaled $472.4 million.

Rationale: The Postal Service believes the current method of allocating attributable empty equipment costs to products should be refined to compute the distribution factors after excluding the portion of costs mapped to component 828 (Total International) that are not transportation related. The accounts recommended to be excluded from the distribution factor calculation are for terminal dues (accounts 53262, 53263, 53268) and for internal conveyance charges (account 53261). These costs are largely the result of settling foreign postal transactions, and are not transportation related. Since there is no apparent causal relationship between variations in non-transportation component 828 costs and empty equipment costs, these non-transportation costs should be eliminated from the distribution factor calculation.

In the current domestic Cost Segment 14 model, all component 828 costs are mapped to the International Mail product group. As a result, including all component 828 costs (transportation and non-transportation) in computing the empty equipment distribution factors causes International Products to be assigned an inequitable proportion of empty equipment costs. Computing the distribution factors after excluding the non-transportation related portion of component 828 costs will result in a fairer distribution of highway and rail empty equipment costs to products. Of course, international mail products are sampled as they travel via the various modes of domestic transportation, and they will therefore continue to be assigned an appropriate share of empty equipment costs on that basis.

Impact: The following table which shows the impact of the proposed change on products (using FY07 mail categories and costs). The proposed methodology results in International Products receiving $9 million less in empty equipment costs, while First Class Mail and Priority Mail each receive $3 million in additional highway and rail empty equipment costs, respectively.

IMPACT OF PROPOSED CHANGES

Class, subclass, or special service	FY 2007 Highway empty equipment costs	FY 2007 Proposed highway empty equipment costs	Highway difference (proposed-current)	FY 2007 Rail empty equipment costs	FY 2007 Proposed rail empty equipment costs	Rail difference (proposed-current)	Highway + rail difference (proposed-current)
First-Class Mail:							
Single-Piece Letters	$10,259	$11,193	934	$4,839	$5,272	433	1,368
Presort Letters	9,863	10,750	887	4,676	5,090	414	1,301
Single-Piece Cards	126	137	11	61	66	5	16
Presort Cards	297	324	27	143	156	13	40
Total First-Class	20,545	22,405	1,860	9,719	10,584	865	2,725
Priority Mail	24,157	26,393	2,236	11,156	12,169	1,012	3,248
Express Mail	1,799	1,964	165	837	912	75	240
Periodicals:							
Within County	2	2	0	1	1	0	0
Outside County	3,633	3,963	330	1,716	1,870	153	483
Total Periodicals	3,635	3,965	330	1,717	1,870	153	484
Standard Mail:							
Enhanced Carrier Route	1,361	1,485	124	636	693	57	181
Regular	6,591	7,183	593	3,125	3,402	277	869
Total Standard Mail	7,951	8,668	717	3,761	4,094	334	1,050
Package Services:							
Parcel Post	5,045	5,508	462	2,355	2,567	212	674
Bound Printed Matter	1,197	1,305	108	568	618	50	159
Media Mail	1,695	1,849	154	806	878	72	226
Total Package Services	7,938	8,662	724	3,729	4,064	334	1,059
U.S. Postal Service	567	620	53	265	289	24	77
Free Mail	79	86	7	38	41	3	10
International Mail	14,409	8,31	(6,091)	6,73	3,930	(2,802)	(8,893)
Total Volume Variable	81,079	81,079	(0)	37,953	37,953	(0)	(0)

Proposal Seven: Proposed Change in Distribution Key for Vehicle Service Driver (VSD) Costs.

Objective: A methodology change is proposed for FY 2008 in the distribution key for Cost Segment 8 (Vehicle Service Drivers) costs.

Background: Cost Segment 8 includes the salaries, benefits, and related costs of vehicle service driver (VSD) labor. VSD workload involves transporting mail using postal-owned and leased vehicles. Transportation runs are made between post offices, branches, Processing and Distribution Centers/Facilities, Air Mail Centers/Air Mail Facilities, Bulk Mail Centers, depots, and certain customer locations.

The attributable costs are calculated by applying the variability factor of 60.44 percent to the accrued costs (approximately $660 million in FY 2007). The volume variability factor was developed in R97–1 (USPS–T–20, Exhibit 2 Revised, page 22). This proposal does not address changing the volume variability factor. In FY 2007, there were approximately $400 million in VSD attributable costs. Currently, after the attributable costs are calculated, they are distributed to products in the same proportions as cubic feet of originating mail obtained from Revenue, Pieces and Weight (RPW) Statistics.

Proposal: The Postal Service is proposing to distribute the attributable costs to products in the same proportions as the estimated cubic-foot miles of mail sampled on Intra-SCF routes. The relevant proportions are developed through the Transportation Cost System (TRACS).

Rationale: The Postal Service submits that the current method of distributing attributable costs to products incorrectly assigns Vehicle Service Driver labor costs to mail that originates at the Destination Delivery Unit (DDU). Presumably, this mail is entered at the DDU for delivery on routes from that office, and thus avoids VSD costs. The current methodology, however, treats all originating mail, regardless of entry point, as incurring the same amount of these labor costs. Absent a specific VSD distribution key, the Postal Service takes the view that a distribution key consisting of the cubic-foot-mile proportions on Intra-SCF runs provides a reasonable proxy for distributing attributable VSD costs to products. Relative proportions of mail transported by Intra-SCF contracts are much more likely to be representative of VSD mail

than relative proportions of originating cube, which necessarily include DDU mail that VSD drivers are unlikely to transport. Intra-SCF highway contracts, by definition, provide local transportation and include some trips from mail processing facilities to delivery units.

Impact: The following table which shows the impact of the proposed change on products (using FY 2007 costs).

IMPACT OF PROPOSED CHANGE ON PRODUCTS

FY 2007 Class, sub-class, or special service	Highway intra-SCF highway	Highway cubic feet	Current highway 2007 CS8 costs	Proposed FY 2007 rail costs using intra-SCF	Proposed minus proposed rail current costs	Current percent	Rail proposed percent
First-Class Mail:							
Single-Piece Letters	$145,729	109,232	$23,408	$69,963	$46,555	5.89	17.60
Presort Letters	56,127	129,637	27,781	26,946	(835)	6.99	6.78
Single-Piece Cards	2,718	971	208	1,305	1,097	0.05	0.33
Presort Cards	4,857	2,852	611	2,332	1,721	0.15	0.59
Total First-Class	209,431	242,692	52,008	100,546	48,538	13.08	25.29
Priority Mail	216,478	398,040	85,298	103,929	18,631	21.46	26.15
Express Mail	11,041	8,334	1,786	5,301	3,515	0.45	1.33
Periodicals:							
Within County	112	10,277	2,202	54	(2,148)	0.55	0.01
Regular	90,696	145,187	31,113	43,542	12,429	7.83	10.95
Total Periodicals	90,807	155,464	33,315	43,596	10,281	8.38	10.97
Standard Mail:							
Enhanced Carr Rte	50,726	226,200	48,473	24,353	(24,120)	12.19	6.13
Regular	116,008	263,241	56,411	55,694	(717)	14.19	14.01
Total Standard Mail	166,734	489,441	104,884	80,047	(24,837)	26.39	20.14
Package Services:							
Parcel Post	70,236	302,504	64,825	33,720	(31,105)	16.31	8.48
Bound Printed Matter	24,648	149,015	31,933	11,833	(20,100)	8.03	2.98
Media Mail	16,447	47,026	10,077	7,896	(2,181)	2.54	1.99
Total Package Services	111,331	498,545	106,835	53,449	(53,386)	26.88	13.45
U.S. Postal Service	8,352	21,612	4,631	4,010	(621)	1.17	1.01
Free Mail	1,808	3,024	648	868	220	16	0.22
International Mail	11,985	37,770	8,094	5,754	(2,340)	2.04	1.45
Total Volume Variable	827,968	1,854,922	397,499	397,499	.....	100.00	100.00

Proposal Eight: [Proposed change to bundle-based mapping for First-Class Mail Automation flats]

Objective: A change in Mail Characteristics Study methodology is proposed to correct an error in the procedure used to map First-Class Mail Automation flats pieces to rate elements in the FY2007 ACR and the two previous rate cases (Docket Nos. R2006–1 and R2005–1).

Background: The methodology used for mapping preparation characteristic to rate element for First-Class Mail Automation flats in R2005–1, R2006–1, and the 2007 ACR was incorrect. These previous Mail Characteristics Studies (*e.g.*, in the 2007 ACR, FY07–14) included a scheme to map automation flats pieces from preparation characteristic to rate element that used a container-based mapping. In fact, however, a bundle-based mapping should apply for automation flats. For example, an automation piece in a 5-digit bundle that is placed in a 3-digit container is assessed the 5-digit rate, and not the 3-digit rate that would be consistent with the presort level of the container. (To give a slightly more complete background, the current container-based mapping scheme was appropriate when designed in anticipation of adoption of a container-based rate structure. The error, so to speak, occurred when the container-based rate structure was never implemented, but, through oversight, the container-based mapped scheme was nonetheless maintained in the spreadsheets, rather than being adapted to a bundle-based mapping scheme to reflect the actual bundle-based rate structure. The intent of this proposal is to correct that oversight.)

Rationale: The bundle-based rates are in effect for automation First-Class Mail flats. Pieces are assessed postage based on the presort level of the bundle, not the presort level of the container.

Impact: The correction of the mapping of preparation characteristic does not alter the aggregate volume of pieces by rate element because RPW rate

element volumes are used as control values. The correction, however, will alter the distribution of pieces across preparation characteristic within rate elements. The effect of the correction will increase the modeled cost for all First-Class Mail Automation flats rate elements. The costs for 5-digit automation pieces increase because the 5-digit rate element includes pieces in 5-digit bundles that have been placed in MADC, ADC or 3-digit tubs and incur additional bundle sorts. In the incorrect versions, the 5-digit automation rate element only included pieces in 5-digit trays, which do not incur bundle sorting costs. The costs of 3-digit automation, ADC automation, and MADC automation pieces increase because these rate elements previously included the relatively lower cost pieces in bundles with a finer bundle presort than the container sort. For example, the 3-digit automation modeled costs included the modeled costs of 5-digit bundles that do not incur as many piece-sorts as pieces in 3-digit bundles. The increase in the modeled costs for each rate element decreases the CRA adjustment factor. As a result of a decrease in the CRA adjustment factor, the non-auto presort rate category costs go down. The effect on the avoided costs is indeterminate because the avoided costs depend on the estimated distribution of pieces across preparation characteristic.

[The following text added by Order No. 102.] On August 18, 2008, Order No. 99 [footnote omitted] established this docket to evaluate eight changes in costing methods that the Postal Service proposes to use in its FY 2008 annual report that it must file under 39 U.S.C. 3652. Later that day, the Commission received the Motion of the United States Postal Service to Supplement the List of Its Proposed Costing Changes for Purposes of Preparing the FY 2008 Annual Compliance Report (Motion). The Motion states that the Postal Service has finalized a ninth proposed change in costing methodology. It requests the Commission to consider its proposal under the procedures and schedule established in Order No. 99.

The Postal Service characterizes this additional proposed change as relatively straightforward. It notes that a description of the proposed change, the rationale for adopting it, and an estimate of the impact of adopting it, accompanies the Motion. Given these circumstances, the Postal Service argues, consideration of this additional proposal could be consolidated with the original eight proposals and evaluated under the procedures outlined in Order No. 99, without detracting from the ability of the postal community to evaluate the original eight.

The Commission agrees. It therefore orders consolidation of the proposed change in costing methods described below with the eight proposals already under consideration in Docket No. RM2008–2.

Proposal Nine: Proposed Change in Distribution Key for PARS Equipment Depreciation, Maintenance Labor, and Parts/Supplies Costs.

Objective: A methodology change is proposed for FY 2008 in the distribution key for the portion of depreciation (cost segment 20.1), maintenance labor (cost segment 11.2), and parts and supplies (cost segment 16.3.2) costs related to Postal Automation Redirection System (PARS) equipment.

Background: PARS equipment is being deployed, replacing the use of Computer Forwarding System (CFS) in the forwarding and return to sender operations for letters. A description of PARS was provided in Docket No. R2006–1 in the testimony of Marc McCrery, USPS–T–42. PARS reduces the costs for processing, transporting and delivery of letters by identifying letter mail that is to be forwarded or returned, at origin. As shown in ACR 2007, USPS–FY07–8, spreadsheet fy07equip.xls, the FY07 depreciation, maintenance labor and parts and supplies for PARS were $59.5, $3.6 and $0.7 million. These will grow in FY08.

These costs, having a volume variability of nearly 100 percent, were distributed to class and subclass in the FY07 CRA based on the distribution key for CFS.

Proposal: The Postal Service is proposing to distribute the attributable costs to products based on the IOCS tallies for the PARS related operations, as done for the distribution key for the PARS related work in the remote encoding centers, LDC 15 (see ACR 2007, USPS–FY07–7, Preface.Part1, page 2).

Rationale: The current method of distributing attributable PARS costs to products, using the CFS distribution, was the best available proxy in the past. But now that PARS tallies are available from the IOCS, there is no reason why the CFS proxy should not be replaced with information directly relating to relative usage of PARS. The current method incorrectly apportions much PARS equipment costs to classes and subclasses that benefit very little from PARS, particularly (because of shape) Periodicals. The proposed PARS distribution key will assign PARS equipment costs to those classes of mail processed with PARS, classes that also obtain the labor savings enabled by PARS.

Impact: The following spreadsheet shows the impact of the proposed change on products (using FY07 costs).

Component name	Component No. cost segment notes	LDC 49—Comp forwarding system (938) 98.1 Set equal to 938 Set W = 0.9992	FY07 Distribution of PARS related costs $ in 000s	FY07 PARS tallies distribution	Distribution based on PARS tallies $ in 000s	Change in distribution by adopting proposal nine $ in 000s
First-Class Mail:						
Single Piece Letters	101	26	16,597	30219.58	19,935	3,338
Presort Letters	102	25	16,138	43172.00	28,480	12,341
Total Letters	103	51	32,736			
Single Piece Cards	104	1	663	3023.10	1,994	1,331
Presort Cards	105	1	701	1663.90	1,098	396
Total Cards	108	2	1,365			
Total First-Class	109	53	34,100			
Priority Mail	110	1	657			(657)
Express Mail	111	0	19			(19)
Periodicals:						
Within County	113	1	516			(516)
Outside County	117	26	16,336	802.05	529	(15,807)
Total Periodicals	123	26	16,852			
Standard Mail:						

Component name	Component No. cost segment notes	LDC 49—Comp forwarding system (938) 98.1 Set equal to 938 Set W = 0.9992	FY07 Distribution of PARS related costs $ in 000s	FY07 PARS tallies distribution	Distribution based on PARS tallies $ in 000s	Change in distribution by adopting proposal nine $ in 000s
Enhanced Carrier Route.	126	1	567	219.81	145	(422)
Regular	127	10	6,688	16238.00	10,712	4,023
Total Standard Mail	135	11	7,256			
Package Services:						
Parcel Post	136	1	516			(516)
Bound Printed Matter	137	2	1,014			(1,014)
Media Mail	139	0	236			(236)
Total Package Services	141	3	1,766			
U.S. Postal Service	142	4	2,499	1076.50	710	(1,789)
Free Mail	147	0	96	222.77		(96)
International Mail	161	0	89		147	57
Total All Mail	162	99	63,336			
Special Services:						
Registry	163	0	64			(64)
Certified	164	0				
Insurance	165	0				
COD	166	0				
Money Orders	168	0				
Stamped Cards	159	0				
Stamped Envelopes	169	0				
Special Handling	170	0				
Post Office Box	171	0				
Other	172	1	351			(351)
Total Special Services	173	1	414			
Total Attributable	198	100	63,750	96637.71	63,750	(0)
Other Costs	199					
Total Costs	200					
		Deprec	$59,476			
		Maintenance Labor	$ 3,627			
		Parts & Supplies	$ 698			
			$63,801			
		Variability	0.99920			
		Total Vol. Var. Costs	$63,750			

III. Ordering Paragraphs

[Order No. 99]

It is Ordered:

1. Docket No. RM2008–3 is established for the purpose of considering the Request of the United States Postal Service for Commission Order Amending the established Costing Methodologies for Purposes of Preparing the FY 2008 Annual Compliance Report, filed August 11, 2008.

2. An informal technical conference to explore and clarify proposals is scheduled for August 27, 2008 at 10 a.m. in the Commission's hearing room.

3. Interested persons may file initial comments on or before September 8, 2008.

4. Reply comments may be filed on or before September 15, 2008.

5. William C. Miller is designated as the Public Representative representing the interests of the general public in this proceeding.

6. The Secretary shall arrange for publication of this Notice in the **Federal Register**.

[Order No. 102]

1. The Motion of the United States Postal Service to Supplement the List of Its Proposed Costing Changes for Purposes of Preparing the FY 2008 Annual Compliance Report, filed August 18, 2008, is granted.

2. The proposal described in this Order will be considered under the current procedural schedule in Docket No. RM2008–2.

3. The Secretary shall arrange for publication of this Notice in the **Federal Register**.

Authority: 39 U.S.C. 3652.

By the Commission.

Judith M. Grady,

Acting Secretary.

[FR Doc. E8–20694 Filed 9–5–08; 8:45 am]

BILLING CODE 7710–FW–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

Office of Postsecondary Education; Notice of Negotiated Rulemaking for Programs Authorized Under Title IV and Title II of the Higher Education Act of 1965, as Amended

AGENCY: Department of Education.

ACTION: Notice of invitation for public comment and establishment of negotiated rulemaking committees.

SUMMARY: We announce our intention to establish negotiated rulemaking committees to prepare proposed regulations under Title IV and, possibly, Title II of the Higher Education Act of 1965, as amended (HEA). The committees will include representatives of organizations or groups with interests that are significantly affected by the subject matter of the proposed regulations. We also announce six public hearings, at which interested parties may suggest issues that should be considered for action by the negotiating committees. In addition, for anyone unable to attend a public hearing, we announce that the Department will accept written comments.

DATES: The dates, times, and locations of the public hearings are listed under the **SUPPLEMENTARY INFORMATION** section of this notice. We must receive written comments suggesting issues that should be considered for action by the

negotiating committees on or before October 8, 2008.

ADDRESSES: Please send written comments to Wendy Macias, U.S. Department of Education, 1990 K Street, NW., room 8017, Washington, DC 20006, or by fax to Wendy Macias at (202) 502–7874. You may also e-mail your comments to *HEOA08@ed.gov*.

FOR FURTHER INFORMATION CONTACT: For information about the public hearings, see *http://www.ed.gov/HEOA* or contact: Mary Miller, U.S. Department of Education, 1990 K Street, NW., room 8066, Washington, DC 20006. Telephone: (202) 502–7824. You may also e-mail your questions about the public hearings to: *Mary.Miller@ed.gov*.

For information about negotiated rulemaking in general, see *The Negotiated Rulemaking Process for Title IV Regulations, Frequently Asked Questions* at *http://www.ed.gov/HEOA*. For further information contact: Wendy Macias, U.S. Department of Education, 1990 K Street, NW., room 8017, Washington, DC 20006. Telephone (202) 502–7526. You may also e-mail your questions about negotiated rulemaking to: *Wendy.Macias@ed.gov*.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the person responsible for information about the public hearings.

SUPPLEMENTARY INFORMATION: We intend to develop proposed regulations to implement the changes made to the Higher Education Act of 1965 (HEA) by the Higher Education Opportunity Act of 2008 (HEOA), Public Law 110–315. Section 492 of the HEA, as amended by the HEOA, requires that, before publishing any proposed regulations to implement programs authorized under Title IV of the HEA, the Secretary obtain public involvement in the development of the proposed regulations. After obtaining advice and recommendations from the public, the Secretary uses a negotiated rulemaking process to develop the proposed regulations. In addition, section 201(2) of the HEOA added a provision to section 207(c) of the HEA that requires the Secretary to submit to a negotiated rulemaking process any regulations the Secretary chooses to develop under amended section 207(b)(2) of the HEA, regarding the prohibition on a teacher preparation program from which the State has withdrawn approval or terminated financial support from accepting or enrolling any student who receives Title IV aid.

We intend to develop proposed regulations by following the negotiated rulemaking procedures in section 492 of the HEA. We anticipate using the negotiated rulemaking procedures in section 492 of the HEA to develop any regulations for the new teacher preparation program provision in section 207(b)(2) of the HEA, although the Secretary is not required to do so. After a complete review of the HEOA and the public comments presented at the public hearings and through written submission, we will publish a subsequent notice (or notices) announcing the specific subject areas for which we intend to establish negotiated rulemaking committees, and a request for nominations for individual negotiators for those committees who represent the interests significantly affected by the proposed regulations.

We anticipate that we will announce our intent to establish most of the negotiated rulemaking committees by the end of this year, with negotiations beginning in February 2009. For subject areas for which implementation must occur more quickly, the schedule will be expedited.

For general information on the implementation of the HEOA, see *http://www.ed.gov/HEOA*.

Public Hearings

We will hold six public hearings for interested parties to discuss the agenda for the negotiated rulemaking sessions. The public hearings will be held on:

- September 19, 2008 at Texas Christian University in Fort Worth, Texas;
- September 29, 2008 at the University of Rhode Island, in Providence, Rhode Island;
- October 2, 2008 at Pepperdine University, in Malibu, California;
- October 6, 2008 at Johnson C. Smith University, in Charlotte, North Carolina;
- October 8, 2008 at the U.S. Department of Education in Washington, DC; and
- October 15, 2008 at Cuyahoga Community College, in Cleveland, Ohio.

The public hearings will be held from 9:00 a.m.–4:00 p.m., local time, with the exception of the hearing at Texas Christian University in Fort Worth, Texas, which will be held from 10:00 a.m.–4:00 p.m., local time. Further information on the public hearing sites, including addresses and directions, is available at *http://www.ed.gov/HEOA*.

Individuals desiring to present comments at the public hearings are encouraged to do so. It is likely that each participant choosing to make a statement will be limited to five minutes. Individuals interested in making oral statements will be able to register to make a statement beginning at 8:30 a.m. on the day of the public hearing (9:30 a.m. on the day of the public hearing for the hearing at Texas Christian University) at the Department's on-site registration table on a first-come, first-served basis. If additional time slots remain, individuals may be given additional time to speak. If no time slots remain, the Department has reserved one additional hour at the end of the day for individuals who were not able to register to speak. The amount of time available will depend upon the number of individuals who register to speak. Speakers may also submit written comments. In addition, for anyone unable to attend a public hearing, the Department will accept written comments through October 8, 2008. (See the **ADDRESSES** sections of this notice for submission information.)

The public hearing sites are accessible to individuals with disabilities. Individuals needing an auxiliary aid or service to participate in a meeting (*e.g.*, interpreting service, assistive listening device, or materials in alternative format), should notify the contact person for information about hearings listed under **FOR FURTHER INFORMATION CONTACT** in this notice in advance of the scheduled meeting date. Although we will attempt to meet any request we receive, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to This Document

You may view this document, 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 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*.

Program Authority: 20 U.S.C. 1098a; Pub. L. 110–315, § 201(2).

Dated: September 3, 2008.

Cheryl A. Oldham,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. E8–20776 Filed 9–5–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 070720390–81114–02]

RIN 0648–AV28

Fisheries in the Western Pacific; Bottomfish and Seamount Groundfish Fisheries; Management Measures for the Northern Mariana Islands

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

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would establish Federal permitting and reporting requirements for all commercial bottomfish vessels fishing in the U.S. Exclusive Economic Zone (EEZ) around the Commonwealth of the Northern Mariana Islands (CNMI). The proposed rule would also close certain EEZ waters around the CNMI to bottomfish fishing by vessels over 40 ft (12.2 m) long. Vessel monitoring system units would be installed on these vessels, and the operators of these vessels would be required to submit Federal sales reports in addition to catch reports. This proposed rule is intended to ensure adequate collection of information about the CNMI commercial bottomfish fishery, provide for sustained community participation, and maintain a consistent supply of locally-caught bottomfish to CNMI markets and seafood consumers. Combined, these measures are intended to prevent the depletion of bottomfish stocks in the CNMI, and to sustain the fisheries that depend on them.

DATES: Comments on this proposed rule must be received by October 23, 2008.

ADDRESSES: Comments on the amendment, identified by 0648–AV28, may be sent to either of the following addresses:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*; or
- Mail: William L. Robinson, Regional Administrator, NMFS, Pacific Islands Region (PIR), 1601 Kapiolani Blvd, Suite 1110, Honolulu, HI 96814–4700.

Instructions: All comments received are a part of the public record and will generally be posted to *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the commenter may be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (if you wish to remain anonymous, enter ''NA'' in the required name and organization fields). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the Fishery Management Plan for Bottomfish and Seamount Groundfish Fisheries of the Western Pacific Region (Bottomfish FMP) and proposed Amendment 10 are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org*.

FOR FURTHER INFORMATION CONTACT: Bob Harman, NMFS PIR, 808–944–2271.

SUPPLEMENTARY INFORMATION: This **Federal Register** document is also accessible at the Office of the **Federal Register** web site *www.gpoaccess.gov/fr*.

The bottomfish fishery around the Northern Mariana Islands is managed under the Bottomfish FMP, which was developed by the Council, and approved and implemented by NMFS. The Council has submitted Bottomfish FMP Amendment 10 to NMFS for review under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This proposed rule would implement the management provisions recommended in Amendment 10, if the amendment is approved by the Secretary of Commerce.

CNMI nearshore areas have been fished for years by bottomfish fishermen who engage in a mix of subsistence, recreational, and small-scale commercial fishing. These fishermen typically operate small vessels (less than 25 ft (7.6 m)), and tend to fish more in the summer months when weather and sea conditions are calmer. Most of these small vessels target shallow-water bottomfish, but some also target deep-water species. The catch from these small vessels is destined for local markets and consumers in the CNMI, and is usually not exported.

In addition to small vessels, several larger vessels (over 40 ft (12.2 m) in length) also target deep-water bottomfish at offshore seamounts and banks. In 2006, for example, there were six large vessels targeting bottomfish around the CNMI. Landings from these large vessels are offloaded on Saipan and in other CNMI commercial ports, and are often exported by air to Japan. Thus, the catch from these large vessels does not enter local markets as a food supply for CNMI residents. If these vessels were to target bottomfish in nearshore waters around CNMI, the resulting fishing pressure could be excessive on bottomfish stocks at nearshore banks, potentially threatening both the fish stocks and the fisheries that have historically been dependent on these resources.

The CNMI is relatively close to Guam, and it is possible for large bottomfish vessels based in Guam to travel to fishing grounds in the CNMI. NMFS recently implemented a final rule that prohibits large vessels (i.e., greater than 50 ft (15.2 m)) from bottomfish fishing within 50 nm (80.5 km) around Guam (71 FR 64474; November 2, 2006). Without similar closed areas around the CNMI, operators of these large Guam-based vessels may choose to fish for bottomfish within U.S. EEZ waters around the CNMI. This could result in excessive fishing pressure on bottomfish stocks at nearshore banks, potentially threatening both the fish stocks and the fisheries that have historically been dependent on these resources.

In addition to the possibility of Guam-based vessels entering the CNMI bottomfish fishery, the Council is concerned about several other issues regarding bottomfish fishing in the CNMI. First, existing data collection programs in the CNMI are insufficient to monitor catches and determine the impacts of the fishery on the bottomfish stocks being harvested, or to determine the species composition and amount of discarded catch. Second, large bottomfish vessels need to harvest relatively large catches to cover operational costs, and these large catches could deplete nearshore stocks. Stock depletion would threaten the sustainability of the CNMI bottomfish fishery, and if catch rates were significantly reduced, small vessels would not be able to continue operating. Finally, because the catches from large vessels are typically exported, traditional patterns of supply and consumption of bottomfish in the local community would be disrupted.

In response to these concerns, the Council developed Amendment 10 with the following objectives: (1) ensure that adequate information is routinely collected for the CNMI offshore

bottomfish fishery; (2) provide for sustained community participation; and (3) encourage the consistent availability of locally-caught deepwater bottomfish to CNMI markets and consumers.

The issues considered here were first raised in 2001 by CNMI members of the Council's Advisory Panel. The Council and its advisory groups discussed these issues during 2001 and 2002, and the Council first took action on the measures contained in this document on February 13, 2003, at its 117th Council meeting held in Saipan, CNMI. A range of alternatives and preliminary analyses of their anticipated impacts were presented for consideration and the Council identified several management recommendations. Following further public comments, at its 118th meeting (June 2003, in Honolulu, Hawaii) the Council again considered this matter and recommended that additional input on the issue and alternatives be solicited from the CNMI government. Correspondence with the CNMI governor, and public input during a series of scoping sessions in the CNMI, led to the development and analysis of a revised set of management recommendations, adopted at the Council's 126th meeting held March 14–17, 2005, in Honolulu, Hawaii. The Council then prepared Amendment 10 (including an environmental assessment) that contains background information on the issue, associated analyses, and proposed regulatory changes for consideration by NMFS. This proposed rule would implement the management measures recommended in Amendment 10.

This proposed rule would require the owners of all vessels commercially fishing for bottomfish management unit species (BMUS) in EEZ waters around the CNMI to obtain Federal fishing permits. Permit eligibility would not be restricted, and permits would be renewable on an annual basis. NMFS has initially determined that a permit fee of $80 is appropriate, but will consider whether a lesser cost is sufficient to cover the administrative costs of the permit. The amount of the permit fee is calculated in accordance with the procedures of the NOAA Finance Handbook for determining the administrative costs of each special product or service incurred in processing the permit. The fee may not exceed such costs and is specified with each permit application form.

This proposed rule would require the operators of all commercial bottomfish vessels to complete and submit Federal catch reports. These daily reports are logbooks that contain the fisherman's record of bottomfish fishing effort, catch, discards, interactions with protected species, and related information. In addition to the fishing logbook, vessels over 40 ft (12.2 m) fishing for bottomfish in the CNMI would be required to complete and submit Federal sales reports for the bottomfish that they sell.

This proposed rule would close certain EEZ waters around the CNMI to bottomfish fishing by vessels over 40 ft (12.2 m). The closed areas would include EEZ waters from the shoreline to 50 nm (80.5 km) around the southern islands of the CNMI, from the Guam-CNMI EEZ boundary to a line halfway between Farallon de Medinilla and Anatahan Islands, and EEZ waters from the shoreline to 10 nm (18.5 km) around the northern island of Alamagan (Fig. 1). The closed area boundaries would be defined by straight lines for clarity and to facilitate enforcement. Transshipping of bottomfish would continue to be allowed within the closed areas. Any vessel commercially receiving bottomfish fish or fish products from a fishing vessel would be required to be registered with a valid CNMI commercial bottomfish permit, and the operator would be required to report any bottomfish transshipping activity in the Federal fishing logbook forms.

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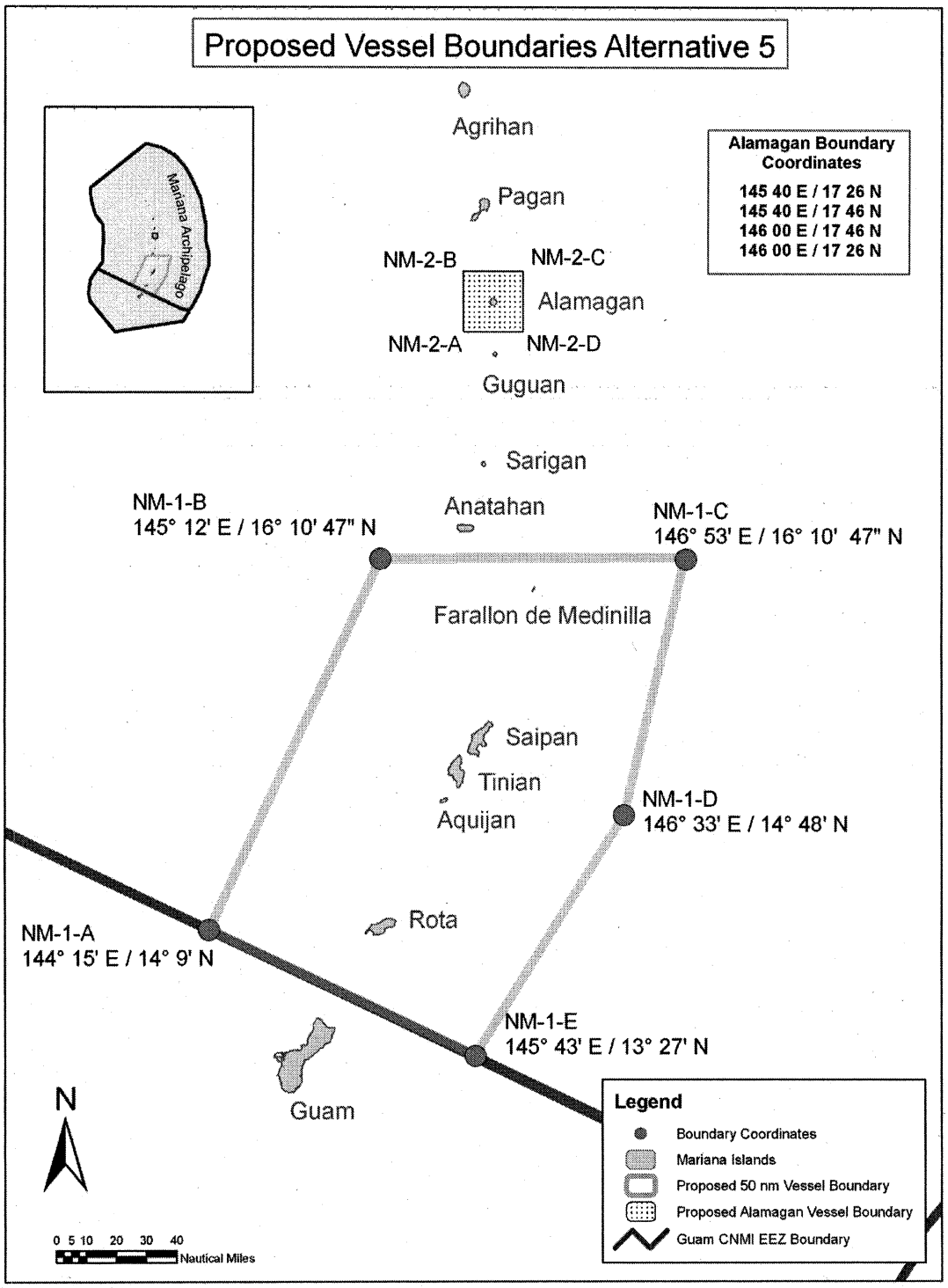

Figure 1. Proposed CNMI medium and large vessel prohibited areas.

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Shipboard vessel monitoring system (VMS) units would be required on vessels over 40 ft (12.2 m). The VMS is an automated, satellite-based system that assists NOAA's Office for Law Enforcement and the U.S. Coast Guard in monitoring compliance with closed areas in a reliable and cost-effective manner. Electronic VMS shipboard equipment installed permanently on board a vessel provides information about the vessel's position and activity. That information is communicated between the shipboard VMS unit and the monitoring agency's fishery monitoring center, where the identity and location of the vessels are shown on a map display, comparing vessel positions with features of interest, such as closed area boundaries. The Pacific

Islands VMS was developed in cooperation with fishermen, fishery managers, the U.S. Coast Guard, and other government agencies, and is currently used in the Hawaii- and American Samoa-based longline fisheries, and in the bottomfish fishery operating in the Papahanaumokuakea Marine National Monument in the Northwestern Hawaiian Islands (NWHI).

CNMI-registered bottomfish vessels are required to be marked with their official number in block lettering of a minimum of three inches (7.6 cm) high. The implementation of the new CNMI commercial bottomfish permit would tie to a related Federal vessel identification requirement in § 665.16 that requires Federal permit holders to mark their vessels in a specific way using much larger lettering. These Federal vessel identification requirements were created for large commercial fishing vessels to assist in aerial and at-sea enforcement of fishing regulations. The typical CNMI-based commercial bottomfish vessel, however, is not large enough to have the superstructure or deckhouse to support the Federal vessel identification markings. The proposed rule would exempt CNMI-based commercial bottomfish vessels from the Federal vessel identification requirements, if the vessels are less than 40 ft (12.2 m) long and in compliance with CNMI vessel registration and marking requirements. Commercial CNMI bottomfish vessels over 40 ft (12.2 m) would be required to be marked in compliance with Federal vessel identification requirements.

To date, the regional requirements for VMS in 50 CFR part 665 have applied only to pelagic longline fishing, so the requirements are located in the pelagic fisheries section of the regulations. (The VMS requirements for the NWHI bottomfish fishery are found in 50 CFR 404.5 and are not affected by this proposed rule.) Because the proposed rule would add VMS requirements for bottomfish fishing, the section regarding the vessel monitoring system (§ 665.25) would be moved from the pelagic fishery requirements to the general requirements and renumbered as § 665.19. Accordingly, the VMS-related prohibitions found in § 665.22 would also be moved to the general prohibitions in § 665.15. The VMS-related requirements would also be clarified to require that VMS units be installed and operational when vessels are at sea.

In the definition of bottomfish management unit species, the scientific name for armorhead is revised to the valid taxonomic name, and the scientific name of the pink snapper is revised to include the species, which was inadvertently omitted from the definition. The spellings of local names of the longtail and pink snappers are also corrected. In the definition of receiving vessel permit, the cross-reference to receiving vessel permits for pelagic longlining is corrected to the proper paragraph.

Comments on this proposed rule must be received by October 23, 2008. To be considered, comments must be received by close of business on October 23, 2008, not postmarked or otherwise transmitted by that date.

In addition to soliciting public comments on this proposed rule, NMFS is soliciting comments on proposed FMP Amendment 10 through October 20, 2008, as stated in the Notice of Availability published on August 20, 2008 (73 FR 49157). Public comments on this proposed rule, if received by October 20, 2008, will also be considered in the approval/disapproval decision for Amendment 10. Comments received after that date may not be considered in the approval/disapproval decision for Amendment 10, but will be considered for this proposed rule.

Classification

Pursuant to section 304 (b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Bottomfish FMP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

The Council prepared an Environmental Assessment for Amendment 10 that evaluates the potential impacts of the proposed action and alternatives. A copy of the environmental assessment is available from the Council (see **ADDRESSES**).

The purpose and need for the proposed action is to monitor the CNMI bottomfish fishery, to sustain community participation in the bottomfish fishery (i.e., small-scale fishing, community exchange, and sale), and to encourage consistent availability of locally-caught bottomfish in the CNMI.

Five alternatives were considered: Alternative 1 - No action, Alternative 2 - Establish a 3–50 nm (5.6–80.5 km) closure for large vessels (over 50 ft (15.2 m)) and other permitting and reporting measures, Alternative 3 - Establish a 250 lb (113 kg) limit for onaga (longtail snapper, *Etelis coruscans*) per trip (all fishermen on the trip combined) outside 3 nm (5.6 km) from the CNMI, Alternative 4 - Limit entry to recent documented fishery participants outside 3 nm (5.6 km) from the CNMI, and 5 - Establish a 50 nm (80.5 km) closure for vessels over 40 ft (12.2 m) and other permitting and reporting measures. Alternative 5 was selected as the preferred alternative. The action would establish a 50 nm (80.5 km) closed area for commercial bottomfish vessels over 40 ft (12.2 m) around the southern islands in the CNMI, and would also establish a 10 nm (18.5 km) closure around the northern island of Alamagan. Vessels over 40 ft (12.2 m) would be required to have VMS units installed, and the operators would be required to submit Federal sales reports for the bottomfish they sell. Alternative 5 would also require Federal fishing permits and data reporting for all commercial bottomfish vessels.

The Council expects that the proposed rule would maintain or improve current levels of bottomfish recruitment and control the risk of localized depletion from nearshore fishing by medium and large vessels. The proposed rule would maintain the opportunity for viable catch rates at banks within the limited fishing range of smaller vessels in the CNMI, which would promote social and economic stability within the community-based fishery and help preserve elements of the local fishing culture. The rule may discourage (but would not prohibit) expansion of the medium and large vessel sectors.

Most CNMI commercial bottomfish vessels are smaller than 40 ft (12.2 m) and generally around 25 ft (7.6 m). There are currently no active large vessels in the fishery. Six vessels larger than 40 ft (12.2 m) were active in 2006, and one in 2007. The closed areas around Saipan and Alamagan would serve to discourage (but would not prohibit) the renewal of a large-vessel export-oriented bottomfish fishery. These large vessels would still be able to fish in waters beyond 50 nm (80.5 km) around the southern CNMI islands, outside of 10 nm (18.5 km) around Alamagan, and in all other waters of the northern CNMI. The permitting and data collection measures would improve information that is available to fishery scientists and managers, and would be used to improve stock assessments and support management measures that achieve optimum yields and maintain a sustainable fishery. The proposed rule would help to ensure the availability of locally-caught bottomfish for CNMI's consumers, enable larger vessels to continue to harvest bottomfish, and continue some opportunities for overseas bottomfish sales.

By reducing the potential for fishing pressure from medium and large vessels, the proposed rule is expected to

reduce the risk of nearshore bottomfish depletion and ensure healthy bottomfish stocks. Catches of non-target fish are low because of the selective nature of the fishing gear used, and these non-target catches are expected to remain low as a result of the reduced fishing effort.

The proposed rule is not expected to have a significant adverse impact on coastal, demersal, or other marine habitats including essential fish habitat or habitat areas of particular concern. The proposed measures are intended to reduce fishing pressure on nearshore bottomfish areas, and would result in a few larger vessels being required to move further offshore. There is a slight potential for increased impacts of bottomfish fishing on the essential fish habitat of offshore banks, but because of the gear types used in the fishery, and the proposed requirements for permits and reporting, the impacts are not expected to be significant.

No significant adverse impacts are expected on protected marine mammals, sea turtles, or seabirds. In general, the CNMI bottomfish and pelagic fisheries are small-scale hook-and-line fisheries with few to no interactions with marine mammals, sea turtles, or seabirds. The proposed rule would reduce fishing pressure within 50 nm (80.5 km) of the CNMI southern islands and 10 nm (18.5 km) of Alamagan Island, and is not expected to result in significant changes in fishing interactions with protected species in other areas.

Positive impacts on the catch rates for small vessels are expected because medium and large commercial bottomfish fishing vessels would be prohibited from fishing near the southern islands and Alamagan. Negative impacts may be expected for medium and large commercial vessels due to increased operating costs associated with fishing beyond the closed area boundaries. This negative impact may be offset by higher bottomfish catch rates in the offshore areas that have been fished to a lesser degree. Given that no large commercial bottomfish vessels are thought to be operating around the southern islands or Alamagan at this time, no immediate impacts are expected and future fishing operations would be able to anticipate the expenses.

There would be additional administrative burdens and costs to NMFS for implementing the proposed rule. These costs would vary depending on the size of the CNMI commercial bottomfish fishery. The Federal permit program is expected to cost $20–35K annually. The cost to establish the data reporting program is estimated to be about $70K, and the annual operating costs, including shoreside monitoring, is estimated at about $100K. The costs to NMFS and the USCG to enforce the permitting, data reporting, and closed area requirements (including the VMS program) are expected to be $372–403K for the first year, and $260–290K annually after that.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows.

Description of Small Entities to Which the Rule Would Apply

The preferred alternative would apply to all vessels commercially fishing for bottomfish in U.S. EEZ waters around CNMI. Given an annual average of 58 known commercial fish harvesting vessels between 2001–05, with an annual average fleet-wide adjusted revenue of $136,827, it is estimated that each vessel operator realized an average of $2,359 in annual ex-vessel gross revenues from their bottomfish fishing operations. Because each vessel has gross receipts under $4.0 million, is independently owned and operated, and is not dominant in its field, all vessels comprising this fishery are deemed to be small entities under the Small Business Administration's definition of a small fish harvester. In 2005, 62 vessels less than 40 ft (12.2 m) participated in the CNMI bottomfish fishery. As many as eleven medium and large vessels (i.e., greater than 40 feet or 12.2 m) are believed to have participated in this fishery since 1997. Information from fisheries officials in the CNMI indicate that there were six active medium and large vessels in 2006, and one in 2007.

Description of Alternatives

Alternative 1: No Action. In the short-term, fishery participants would be expected to continue their normal operations. In the longer-term, economic impacts (including market and non-market impacts) on small-vessel commercial, recreational, and charter fishery participants could be negative if localized depletion of bottomfish occurs within their limited fishing range. Due to their larger vessel sizes, larger-scale commercial bottomfish operations (which are still considered small entities) would still have access to offshore fishing areas. Smaller vessels would not, however, and could see bigger losses. Operators of the smaller vessels already generally participate in more than one fishery over the course of a year, and would likely shift their bottomfish fishing effort to other boat-based fisheries (e.g., pelagic trolling). Whether or not they would be able to recoup their lost bottomfish income is unclear, but a disruption of the nearshore bottomfish fishery would represent a reduction in their portfolio of fishing opportunities.

Alternative 2: Prohibit commercial fishing for bottomfish management unit species (BMUS) by vessels greater than 50 ft (15.2 m) within U.S. EEZ waters 3–50 nm (5.6–80.5 km) around the CNMI; require that operators of vessels greater than 50 ft (15.2 m) that land BMUS in the CNMI have Federal fishing permits and submit Federal logbooks of their associated catch and effort. Alternative 2 may have more positive impacts than Alternative 1 for small-vessel commercial, recreational, and charter fishery participants by maintaining the opportunity for viable catch rates at banks within their limited fishing range around the CNMI. Unlike Alternative 1, Alternative 2 could cause negative impacts on the large-vessel commercial sector of the fishery (whose participants are still considered small entities) through the realization of increased operating costs necessitated by the requirement that large vessels fish on banks greater than 50 nm (80.5 km) from the CNMI, although this impact might be offset initially by higher bottomfish catch rates at more distant seamounts that remain open to large vessels. Likely areas for bottomfish fishing more than 50 nm (80.5 km) from shore are a chain of seamounts, some rising to shallow depths, about 200 nm (370 km) west of the Mariana Islands. As these areas have not been previously fished by the CNMI fleet, there would be a high cost associated with exploring the bottomfish fishing potential of these seamounts and their catch rates are unknown.

As compared to the No Action Alternative, Alternative 2 would eliminate commercial bottomfish fishing by large vessels (still considered small entities for purposes of this analysis) in waters 3–50 nm (5.6–80.5 km) around the CNMI. There may be immediate impacts to vessel operations under this alternative as there may be some large commercial bottomfish fishing vessels active in waters within 50 nm (80.5 km) of the Northern Islands, though none is believed to be active in waters around the Southern Islands. This alternative would eliminate the potential renewal or expansion of the large vessel fishery sector in waters around Saipan. Thus, Alternative 2 would have greater potential than Alternative 1 for reducing the risk of local depletion of areas around Saipan that are fished by small-scale fishermen. A chain of seamounts lies parallel to the Mariana Archipelago nearly 200 nm (370 km) to the west. Some of these seamounts rise to shallow depths, but the seamounts are poorly-charted and the associated bottomfish habitat is not known. Whether or not large vessels would invest time and money in exploring these seamounts for bottomfish grounds under this alternative is unknown. In the long-term, this alternative would foreclose the opportunity for commercial bottomfish fishing using large vessels in the closed areas.

This alternative would require the operators of CNMI-based vessels larger than 50 ft (15.2 m) commercially fishing for bottomfish in U.S. EEZ waters around the CNMI to obtain Federal fishing permits and to submit Federal catch reports. Permit eligibility would not be restricted, and the permit would be renewable on an annual basis. It is anticipated that initial permit applications would require 0.5 hr per applicant, with renewals requiring an additional 0.5 hr annually. No special skills beyond the ability to read and write in English would be required to complete the permit application, logbooks or sales reports. The fee for the proposed Federal fishing permit is proposed to be $80, and would be calculated in accordance with the procedures of the NOAA Finance Handbook for determining the administrative costs of each special product or service incurred in processing the permit. In developing the final rule, NMFS may consider whether a lesser permit fee is appropriate. A $20 permit fee would represent approximately 0.8 percent of revenues earned by individual vessels in the 2001–05 fishery. Similarly, a $40 permit fee would represent about 1.7 percent, a $60 fee would be about 2.6 percent, and an $80 fee would represent about 3.4 percent of revenues earned by individual vessels in the 2001–05 fishery.

Alternative 3: Limit onaga landings to no more than 250 lb (113 kg) per trip for any vessel fishing in U.S. EEZ waters beyond 3 nm (5.6 km) around the CNMI. Alternative 3 would be expected to yield beneficial economic impacts for small vessels that target onaga (longtail snapper). They would be expected to maintain their opportunities for viable onaga catch rates at banks within their limited fishing range, as the reduced fishing revenues expected with a per-trip limit of 250 lb (113 kg) of onaga would discourage competition from large-scale, commercial onaga-fishing operations. Economic impacts on these large-scale operations (still considered small entities) would be adverse, as a 250–lb (113–kg) trip limit would not yield enough revenues to cover trip costs, and these trips would be expected to become economically inefficient. This would be expected to discourage medium/large vessels from entering the fishery.

Alternative 4: Establish a limited access program with Federal permit and reporting requirements, for vessels targeting BMUS more than 3 nm (5.6 km) around the CNMI. Alternative 4 would likely have a positive economic impact on catch rates and ex-vessel revenues for fishery participants who have a documented history of bottomfish fishing in the U.S. EEZ, but a negative impact for undocumented or future potential participants. Limiting total fishery participation would be expected to result in increased catch rates for qualifying participants, fishing efficiency, and profits for those who qualify and continue fishing. Economic impacts on existing and future non-qualifiers would be highly adverse, with no bottomfish catches or revenues available for this group. If limited-access permits were transferable, this alternative would also create an economic value for these permits, as the original qualifiers could subsequently sell or lease them to a new round of participants. This would represent a windfall profit to the original qualifiers.

This alternative would require the operators of all CNMI-based vessels commercially fishing for bottomfish in U.S. EEZ waters around the CNMI to obtain Federal fishing permits and to submit Federal catch reports. Permit eligibility would not be restricted in any way, and permits would be renewable on an annual basis. It is anticipated that initial permit applications would require 0.5 hr per applicant, with renewals requiring an additional 0.5 hr annually. The fee for the proposed Federal fishing permit is proposed to be $80, and would be calculated in accordance with the procedures of the NOAA Finance Handbook. A $20 permit fee would represent approximately 0.8 percent of revenues earned by individual vessels in the 2001–05 fishery. Similarly, a $40 permit fee would represent about 1.7 percent, a $60 fee would be about 2.6 percent, and an $80 fee would represent about 3.4 percent of revenues earned by individual vessels in the 2001–05 fishery. Based on experience in other fisheries, it is expected that the time requirement for filling out Federal catch reports would be approximately 20 min per vessel per fishing day. No special skills beyond the ability to read and write in English would be required to complete the permit application, logbooks or sales reports.

Alternative 5 (Preferred): Prohibit commercial fishing for BMUS by medium and large vessels within U.S. EEZ waters 0–50 nm (0–80.5 km) around CNMI in the area from the southern boundary of the EEZ (south of Rota) to the north latitude of 16 10' 47'' (halfway between Farallon de Medinilla to Anatahan) and within EEZ waters 0–10 nm (0–18.5 km) around Alamagan Island; require that medium and large vessels fishing commercially for BMUS in EEZ waters around the CNMI carry operating VMS units, and complete Federal sales reports for any BMUS sold in the CNMI; require that operators of all vessels fishing commercially for BMUS in EEZ waters around the CNMI have Federal fishing permits and submit Federal logbooks of their associated catch and effort. The impacts of Alternative 5 on commercial bottomfish vessels over 40 ft (12.2 m) would be similar to those of Alternative 2. However, the impacts to the catch rates and ex-vessel revenues of small-vessel fishermen would be more pronounced, as medium and large commercial bottomfish fishing vessels (though still considered small entities) would be prohibited from fishing around the southern islands and Alamagan. The recent general absence of such vessels from the fishery suggests that the area is not profitable for these vessels, and fishing in the restricted area may be more opportunistic than planned. Therefore, restricting medium and large vessels in the area may yield only a minimal adverse economic impact to individual vessels, mitigated by profitable opportunities elsewhere.

This alternative would require the operators of all CNMI-based vessels commercially fishing for bottomfish in U.S. EEZ waters around the CNMI to obtain Federal fishing permits and to submit Federal catch reports. Permit eligibility would not be restricted in any way, and the permit would be renewable on an annual basis. It is anticipated that initial permit applications would require 0.5 hr per applicant, with renewals requiring an additional 0.5 hr annually. The fee for the proposed Federal fishing permit is proposed to be $80, and would be calculated in accordance with the procedures of the NOAA Finance Handbook. A $20 permit fee would represent approximately 0.8 percent of revenues earned by individual vessels in the 2001–05 fishery. Similarly, a $40 permit fee would represent about 1.7 percent, a $60 fee would be about 2.6 percent, and an $80 fee would represent about 3.4 percent of revenues earned by individual vessels in the 2001–05 fishery. Based on experience in other fisheries, it is expected that the time requirement for filling out Federal catch reports would be approximately 20 min per vessel per fishing day. No special skills beyond the ability to read and write in English would be required to complete the permit application, logbooks and sales reports.

This proposed rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), including permits, catch and sales reports, vessel identification, and VMS. These requirements have been submitted to OMB for approval. Permit eligibility would not be restricted in any way, and the permit would be renewable on an annual basis. The Council anticipates that initial permit applications would require 0.5 hours per applicant, with renewals requiring an additional 0.5 hours annually. It is estimated that NMFS may receive and process up to 50 to 125 permit applications each year. Thus, the total collection-of-information burden to fishermen for permit applications is estimated at 25 to 62 hours per year. NMFS has initially determined that a permit fee of $80 is appropriate, but will consider whether a lesser cost is sufficient to cover the administrative costs of the permit.

The proposed rule would also require the operators of all vessels commercially fishing for bottomfish in U.S. EEZ waters around the CNMI to complete and submit Federal catch reports. The Council anticipates the time requirement to complete Federal catch reports to be approximately 20 minutes per vessel per fishing day. Assuming that the 50 to 125 vessels make 10 to 50 trips per year, and average 1.2 days per trip, the program would generate in the range of 600 to 7,500 daily fishing logbooks per year. Thus, the total collection-of-information burden estimate for fishing data reporting is estimated at 200 to 2,500 hours per year.

The proposed rule would also require the operators of medium and large commercial bottomfish vessels to complete and submit Federal sales reports. The Council anticipates the time requirement for completing Federal sales reports to be approximately 35 minutes per vessel per fishing trip. Assuming six medium and large vessels make 15 trips per year, the program would generate approximately 90 sales reports per year. Thus, the total collection-of-information burden estimate for sales data reporting by fishermen is estimated at 52 hours per year. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the information.

For the medium and large vessel identification requirements, the burden is estimated at 45 minutes to paint each vessel (15 minutes for each of three locations on the vessel where marking is required), and about $10 for paint and supplies. Assuming six medium and large bottomfish vessels are active, the total collection-of-information burden estimate is 4.5 hours and $60.

For the medium and large vessel VMS requirements, the estimated time per response is four hours to install a VMS unit, and two hours per year to repair and maintain a VMS unit. Assuming six medium and large bottomfish vessels are active, the total collection-of-information burden estimate for compliance with VMS requirements is 24 hours the first year and 12 hours annually after that.

Public comment is sought regarding: whether this proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collections of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to William L. Robinson (see **ADDRESSES**), and by email to *David_Rostker@omb.eop.gov* or by fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to 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.

List of Subjects in 50 CFR Part 665

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaii, Hawaiian Natives, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: August 29, 2008.

James W. Balsiger,

Acting Assistant Administrator For Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 665 is proposed to be amended as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

1. The authority citation for part 665 continues to read as follows:

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

2. In § 665.12, add the definitions of ''CNMI commercial bottomfish permit'', ''Medium vessel'', and ''Receiving vessel'' in alphabetical order, and in the definition of ''Bottomfish management unit species'' revise the Hawaiian local name of longtail snapper and the Samoan local name and scientific name of pink snapper, in the definition of ''Seamount groundfish'' revise the scientific name of armorhead, and revise the definitions of ''Receiving vessel permit'' and ''Vessel monitoring system unit'' to read as follows:

§ 665.12 Definitions.

* * * * *

Bottomfish management unit species means the following fish:

Common name	Local name	Scientific name
	* * * * *	
Longtail snapper	Onaga, ula′ula (H); palu-loa (S)	*Etelis coruscans.*
	* * * * *	
Pink snapper	Opakapaka (H); palu-ena ′ena (S); gadao (G)	*Pristipomoides filamentosus.*
	* * * * *	

* * * * *

CNMI commercial bottomfish permit means the permit required by § 665.61 (a)(5) to engage in commercial fishing for bottomfish management unit species in U.S. EEZ waters around the CNMI.

* * * * *

Medium vessel, as used in §§ 665.61 through 665.72, means any vessel equal to or more than 40 ft (12.2 m) and less than 50 ft (15.2 m) in length overall.

* * * * *

Receiving vessel means a vessel that receives fish or fish products from a fishing vessel, and with regard to a vessel holding a permit under § 665.21(e) that also lands Pacific Pelagic Management Unit Species taken by other vessels using longline gear.

Receiving vessel permit means a permit required by § 665.21(e) for a receiving vessel to transship or land Pacific pelagic management unit species taken by other vessels using longline gear.

* * * * *

Seamount groundfish means the following species:

Common name	Scientific name
Armorhead	*Pseudopentaceros richardsoni*
* *	* * *

* * * * *

Vessel monitoring system unit (VMS unit) means the hardware and software owned by NMFS, installed on vessels by NMFS, and required to track and transmit the positions of certain vessels.

* * * * *

3. In § 665.13, revise paragraphs (f)(2)(i) through (f)(2)(v), and add a new paragraph (f)(2)(vi) to read as follows:

§ 665.13 Permits and fees.

* * * * *

(f) *Fees.* * * *

(2) * * *

(i) Hawaii longline limited access permit.

(ii) Mau Zone limited access permit.

(iii) Coral reef ecosystem special permit

(iv) American Samoa longline limited access permit.

(v) Main Hawaiian Islands non-commercial bottomfish permit.

(vi) CNMI commercial bottomfish permit.

* * * * *

4. In § 665.14, revise paragraphs (a)(1), (a)(2)(i), and (c) to read as follows:

§ 665.14 Reporting and recordkeeping.

(a) *Fishing record forms*—(1) *Applicability*. The operator of any fishing vessel subject to the requirements of §§ 665.21, 665.41, 665.61(a)(2), 665.61(a)(3), 665.61(a)(4), 665.61(a)(5), 665.81, or 665.602 must maintain on board the vessel an accurate and complete record of catch, effort, and other data on paper report forms provided by the Regional Administrator, or electronically as specified and approved by the Regional Administrator. All information specified by the Regional Administrator must be recorded on paper or electronically within 24 hours after the completion of each fishing day. The logbook information, reported on paper or electronically, for each day of the fishing trip must be signed and dated or otherwise authenticated by the vessel operator in the manner determined by the Regional Administrator, and be submitted or transmitted via an approved method as specified by the Regional Administrator, and as required by this paragraph (a).

(2) *Timeliness of submission*. (i) If fishing was authorized under a permit pursuant to §§ 665.21, 665.41, 665.61(a)(3), 665.61(a)(5), or 665.81, the vessel operator must submit the original logbook form for each day of the fishing trip to the Regional Administrator within 72 hours of the end of each fishing trip, except as allowed in paragraph (a)(2)(iii) of this section.

* * * * *

(c) *Sales report*. The operator of any fishing vessel subject to the requirements of § 665.41, or the owner of a medium or large fishing vessel subject to the requirements of § 665.61(a)(5), must submit to the Regional Administrator, within 72 hours of offloading crustacean or bottomfish management unit species, respectively, an accurate and complete sales report on a form provided by the Regional Administrator. The form must be signed and dated by the fishing vessel operator.

* * * * *

§ 665.22 [Amended]

5. Redesignate paragraphs (o) through (u) in § 665.22 as paragraphs (m) through (s) in § 665.15, and revise newly-redesignated paragraphs (m) through (s) in § 665.15 to read as follows:

§ 665.15 Prohibitions.

* * * * *

(m) Fish for, catch, or harvest management unit species with longline gear without an operational VMS unit on board the vessel after installation of the VMS unit by NMFS, in violation of § 665.19(e)(2).

(n) Possess management unit species, that were harvested after NMFS has installed the VMS unit on the vessel, on board that vessel without an operation VMS unit, in violation of§ 665.19(e)(2).

(o) Interfere with, tamper with, alter, damage, disable, or impede the operation of a VMS unit or attempt any of the same; or move or remove a VMS unit without the prior permission of the SAC in violation of § 665.19(e)(3).

(p) Make a false statement, oral or written, to an authorized officer, regarding the use, operation, or maintenance of a VMS unit, in violation of § 665.19(e)(1).

(q) Interfere with, impede, delay, or prevent the installation, maintenance, repair, inspection, or removal of a VMS unit, in violation of § 665.19(e)(1).

(r) Interfere with, impede, delay, or prevent access to a VMS unit by a NMFS observer, in violation of § 665.28(f)(4).

(s) Connect or leave connected additional equipment to a VMS unit without the prior approval of the SAC, in violation of § 665.19(f).

6. In § 665.16, add new paragraph (e)(2) to read as follows:

§ 665.16 Vessel identification.

* * * * *

(e) * * *

(2) A vessel less than 40 ft (12.2 m) in length registered for use under a CNMI commercial bottomfish permit that is in compliance with CNMI bottomfish vessel registration and marking requirements.

§ 665.25 [Redesignated as § 665.19]

7. Redesignate § 665.25 as new § 665.19, and revise newly-redesignated § 665.19 to read as follows:

§ 665.19 Vessel monitoring system.

(a) *Applicability*. The holder of any of the following permits is subject to the vessel monitoring system requirements in this part:

(1) Hawaii longline limited access permit issued pursuant to § 665.21(b);

(2) American Samoa longline limited entry permit, for vessel size Class C or D, issued pursuant to § 665.21(c);

(3) Vessels permitted to fish in Crustaceans Permit Area 1 VMS Subarea; or

(4) CNMI commercial bottomfish permit, if the vessel is a medium or large bottomfish vessel, issued pursuant to§ 665.61(a)(5).

(b) *VMS unit*. Only a VMS unit owned by NMFS and installed by NMFS complies with the requirement of this subpart.

(c) *Notification*. After a permit holder subject to this part has been notified by the SAC of a specific date for installation of a VMS unit on the permit holder's vessel, the vessel must carry and operate the VMS unit after the date scheduled for installation.

(d) *Fees and charges*. During the experimental VMS program, the holder of a permit subject to this part shall not be assessed any fee or other charges to obtain and use a VMS unit, including the communication charges related directly to requirements under this section. Communication charges related to any additional equipment attached to the VMS unit by the owner or operator shall be the responsibility of the owner or operator and not NMFS.

(e) *Permit holder duties*. The holder of a permit subject to this part, and master of the vessel, must:

(1) Provide opportunity for the SAC to install and make operational a VMS unit after notification.

(2) Carry and continuously operate the VMS unit on board whenever the vessel is at sea.

(3) Not remove, relocate, or make non-operational the VMS unit without prior approval from the SAC.

(f) *Authorization by the SAC*. The SAC has authority over the installation and operation of the VMS unit. The SAC may authorize the connection or order the disconnection of additional equipment, including a computer, to any VMS unit when deemed appropriate by the SAC.

8. In § 665.61, add new paragraph (a)(5) to read as follows:

§ 665.61 Permits.

(a) * * *

(5) *Commonwealth of the Northern Mariana Islands (CNMI) commercial*. The owner of any vessel used to commercially fish for, transship, receive, or land bottomfish management unit species shoreward of the outer boundary of the CNMI management subarea must have a permit issued under this section, and the permit must be registered for use with that vessel.

* * * * *

9. In § 665.62, add paragraphs (o) through (r) to read as follows:

§ 665.62 Prohibitions.

* * * * *

(o) Use a vessel to fish commercially for bottomfish management unit species shoreward of the outer boundary of the CNMI subarea without a valid CNMI commercial bottomfish permit registered for use with that vessel, in violation of § 665.61(a)(5).

(p) Use a medium or large vessel to fish for bottomfish management unit species within the CNMI medium and large vessel bottomfish prohibited areas, as defined in § 665.70(b).

(q) Retain, land, possess, sell, or offer for sale, shoreward of the outer boundary of the CNMI subarea, bottomfish management unit species that were harvested in violation of § 665.62(p), except that bottomfish management unit species that are harvested legally may be transferred to a receiving vessel shoreward of the outer boundary of the CNMI medium and large vessel bottomfish prohibited area as defined in § 665.70(b).

(r) Falsify or fail to make, keep, maintain, or submit a Federal logbook as required under § 665.14(a) when using a vessel to engage in commercial fishing for bottomfish management unit species shoreward of the outer boundary of the CNMI subarea in violation of § 665.14(a).

10. In § 665.69, remove paragraph (a)(7) and redesignate paragraph (a)(8) as paragraph (a)(7), and revise paragraph (a) introductory text, paragraphs (a)(6), and (c) to read as follows:

§ 665.69 Management subareas.

(a) The bottomfish fishery management area is divided into subareas with the following designations and boundaries:

* * * * *

(6) *CNMI Management Subarea* means the EEZ seaward of the CNMI. The CNMI Management Subarea is further divided into subareas with the following designations and boundaries:

(i) *CNMI Inshore Area* means that portion of the EEZ within 3 nautical miles of the shoreline of the CNMI.

(ii) *CNMI Offshore Area* means that portion of the EEZ seaward of 3 nautical miles from the shoreline of the CNMI.

* * * * *

(c) The outer boundary of each fishery management area is a line drawn in such a manner that each point on it is 200 nautical miles from the baseline from which the territorial sea is measured, or is coterminous with adjacent international maritime boundaries, except that the outer boundary of the CNMI Inshore Area is 3 nautical miles from the shoreline. The boundary between the fishery management areas of Guam and the CNMI extends to those points which are equidistant between Guam and the island of Rota in the CNMI.

11. Revise § 665.70 to read as follows:

§ 665.70 Bottomfish fishery area management.

(a) *Guam large vessel bottomfish prohibited area (Area GU–1).* A large vessel of the United States may not be used to fish for bottomfish management unit species in the Guam large vessel bottomfish prohibited area, defined as the U.S. EEZ waters surrounding Guam that are enclosed by straight lines connecting the following coordinates in the order listed:

Point	N. lat.	E. long.
GU–1–A	14°16′	144°17′
GU–1–B	13°50′	143°52′
GU–1–C	13°17′	143°46′
GU–1–D	12°50′	143°54′
GU–1–E	12°30′	144°14′
GU–1–F	12°25′	144°51′
GU–1–G	12°57′	145°33′
GU–1–H	13°12′	145°43′
GU–1–I	13°29′44″	145°48′27″
GU–1–A	14°16′	144°17′

(b) *CNMI medium and large vessel bottomfish prohibited areas.* A medium or large vessel of the United States may not be used to fish commercially for bottomfish management unit species in the following areas:

(1) *CNMI Southern Islands (Area NM–1).* The CNMI Southern Islands prohibited area is defined as the waters of the U.S. EEZ surrounding the CNMI that are enclosed by straight lines connecting the following coordinates in the order listed:

Point	N. lat.	E. long.
NM–1–A	14°9′	144°15′
NM–1–B	16°10′47″	145°12′
NM–1–C	16°10′47″	146°53′
NM–1–D	14°48′	146°33′
NM–1–E	13°27′	145°43′
NM–1–A	14°9′	144°15′

(2) CNMI Alamagan Island (Area NM–2). The CNMI Alamagan Island prohibited area is defined as the waters of the U.S. EEZ surrounding the CNMI that are enclosed by straight lines connecting the following coordinates in the order listed:

Point	N. lat.	E. long.
NM–2–A	17°26′	145°40′
NM–2–B	17°46′	145°40′
NM–2–C	17°46′	146°00′
NM–2–D	17°26′	146°00′
NM–2–A	17°26′	145°40′

[FR Doc. E8–20774 Filed 9–5–08; 8:45 am]

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Notices

Federal Register

Vol. 73, No. 174

Monday, September 8, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Privacy Act of 1974; Abolish Obsolete System of Records

AGENCY: Office of the Secretary, U.S. Department of Agriculture (USDA).

ACTION: Notice of abolishment for USDA/FS–13 Geometronics Skills Inventory record system.

SUMMARY: A review of this Privacy Act System of Records has concluded that this system is no longer in effect and obsolete. This system is being abolished from the Forest Service System of Records in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This notice is effective on September 8, 2008.

ADDRESSES: For additional information contact the Director of Engineering, 1400 Independence Avenue, SW., Mailstop 1101, Washington, DC 20250–1101.

FOR FURTHER INFORMATION CONTACT: Richard W. Sowa, P.E., Director of Engineering, Telephone: (703) 605–4646.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 (5 U.S.C. 552a), as amended, requires that each agency publish a notice of the existence and character of each new or altered ''system of records.'' 5 U.S.C. 552a(a)(5). This notice identifies and abolishes a Forest Service discontinued and obsolete system of records. The Forest Service is abolishing the following system of records which, upon review, is no longer used and is obsolete: USDA/FS–13 Geometronics Skills Inventory. The records have been destroyed according to the Federal Records Disposal Act of 1943 (44 U.S.C. 366–380) and the Federal Records Act of 1950, and as designated in the Forest Service Records Management Handbook (FSH) 6209.11.

Dated: August 22, 2008.

Edward T. Schafer,

Secretary.

[FR Doc. E8–20685 Filed 9–5–08; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Food Safety Inspection Service

[Docket No. FSIS 2008–0028]

Irradiation as a Processing Aid

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Notice of availability of petition and public meeting; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it has received a petition from the American Meat Institute (AMI) to recognize the use of low penetration and low dose electron beam irradiation on the surface of chilled beef carcasses as a processing aid. Based on its consideration of the data and information contained in the petition, FSIS believes that the petition has merit. FSIS will hold a public meeting on September 18, 2008, to review the information contained in the petition and to receive public comments on what action it should take with respect to the petition. A copy of the petition is available on the FSIS Web site.

DATES: The public meeting will be held on September, 18, 2008. Comments must be received by October 18, 2008.

ADDRESSES: The public meeting will be held from 9 a.m. to 1 p.m. at: L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024, (202) 484–1000.

FSIS invites interested persons to submit comments on the petition and its reaction to the petition. FSIS will finalize an agenda on or before the meeting date and will post it on the FSIS Web page *http://www.fsis.usda.gov/News?Meetings_&_Events/*. The petition discussed in this notice is available for viewing by the public in the FSIS Docket Room and on the FSIS Web site *http://www.fsis.usda.gov/News?Meetings_&_Events/* and *http://www.usda.gov/regulations_&policies/Petitions/index.asp*. The official transcript of the meeting will be available for viewing by the public in the FSIS Docket Room and on the FSIS Web site *http://www.fsis.usda.gov/News?Meetings_&_Events/* when it becomes available.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select the FDMS Docket Number FSIS–2008–0028 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, FSIS Docket Room, 1400 Independence Avenue, SW., Room 2534, Washington, DC 20250.

All submissions received must include the Agency name and docket number FSIS–2008–0028. Documents referred to in this notice, and all comments submitted in response to this notice will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2008_Notices_Index/index.asp*.

Individuals who do not wish FSIS to post their personnel contact information—mailing address, e-mail address, telephone number-on the Internet may leave this information off of their comments.

FOR FURTHER INFORMATION CONTACT: For technical information, Patrick Burke: telephone—202/720–7974 and e-mail—*patrick.burke@fsis.usda.gov.*

Pre-registration for this meeting is recommended. To pre-register, please contact Robert Tynan by telephone at (202) 720–3884 or by e-mail at *Robert.Tynan@fsis.usda.gov*, Persons

requiring a sign language interpreter or special accommodations should contact Robert Tynan as soon as possible.

SUPPLEMENTARY INFORMATION:

I. Background

A. Food Irradiation

Food is most often irradiated commercially to extend shelf-life, eliminate insect pests, or reduce numbers of pathogenic microorganisms. Food irradiation for these purposes is practiced in many countries, including the United States. Food irradiation is the process of exposing food to high levels of radiant energy. One form of radiant energy used commercially is electron beam (e-beam). Energy from accelerated electrons is absorbed as they enter the surface of the product being irradiated. The electrons cause chemical bond breakage in the microorganisms immediately, in addition to damaging their deoxyribonucleic acid (DNA). However, not all microorganisms are destroyed at the same energy dose because of the differences in the amount of genetic material or their ability to repair their genetic material.

In 1999, FSIS amended its regulations (64 FR 72168, December 23, 1999) to permit the use of ionizing radiation for treating refrigerated or frozen, uncooked meat, meat by products, and certain other meat food products to reduce levels of foodborne pathogens and to extend shelf-life. The FSIS regulations require the use of sources of ionizing radiation identified in FDA's regulations (21 CFR 179.261(a)). These sources include gamma rays, electrons generated from machine sources (e-beam), and x-rays. In 9 CFR 424.22(c), FSIS details the requirements for the use of irradiation by official establishments, including the labeling requirements for irradiated meat (9 CFR 424.22(c)(4)). The Agency requires that labeling for packaged meat food products irradiated in their entirety bear the radura logo along with a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' FSIS requires that the logo be placed prominently and conspicuously in conjunction with the required statement, and that the statement appear as a qualifier contiguous to the product name (9 CFR 424.22(c)(4)(i)). Also, FSIS requires that inclusion of an irradiated meat food product ingredient in any multi-ingredient product be reflected in the ingredient statement on the finished product labeling (9 CFR 424.22(c)(4)(iii)). FSIS requires that for unpackaged meat food products irradiated in their entirety, the logo and a statement be prominently and conspicuously displayed to purchasers either through labeling on a bulk container or some other appropriate device (9 CFR 424.22 (c)(4)(iii)).

In 21 CFR 179.26 (b), FDA lists the conditions under which ionizing radiation can be safety used. For the control of foodborne pathogens in, and extension of the shelf-life of, refrigerated uncooked meat, the amount of irradiation is not to exceed 4.5 kGy maximum for refrigerated products. The regulation does not list a minimum dose.

B. Processing Aids

Under FDA's regulations, processing aids include substances that are added to a food for their technical or functional effect during processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food (21 CFR 101.100 (a)(3)(ii)(c)). FDA's regulations provide that processing aids are not required to be included on product labels.

FSIS has relied on the FDA regulations on processing aids in regulating the labeling of meat and poultry products (*http://www.fsis.usda.gov/PDF/Determination_of_Processing_Aids.pdf*). FSIS does not require that the use of substances determined to be processing aids be declared on product labels. For example, for over a decade, the Agency has permitted the use of lactic acid and certain other organic acids as antimicrobial carcass washes applied post-slaughter but pre-chiller. In this application, lactic acid and the other organic acids are classified as a processing aid, and no labeling is needed, because the effect of application of the substance is momentary and not lasting.

AMI Petition

On July 8, 2005, AMI submitted a citizen's petition to FSIS requesting that the Agency officially recognize low dose, low penetration e-beam irradiation applied to the surface of chilled beef carcasses as a ''processing aid.'' The petition requested that information concerning irradiation treatment not be required on the label of any products derived from the carcass.

The petition argues that low dose (≤ 1.0 kGy surface dose), low penetration (20mm) e-beam irradiation is a processing aid because the electron beam has a functional effect of reducing pathogens on the carcass surface, but that once the energy from the electrons is absorbed, there were no further functional effects from the irradiation. According to the petition, low dose, low penetration e-beam application results in only a small portion of the carcass receiving the e-beam irradiation exposure. The petition presents evidence that the use of e-beam irradiation is effective in reducing levels of *Escherichia coli* O157:H7 on the carcass; has no effect on organoleptic properties or appearance of the carcass; has no lasting effect on shelf life of the carcass or of product derived from the carcass; and produces no significant loss of either macro- or micro-nutrients in the carcass or the product derived from the carcass. A summary of the scientific data presented in the petition follows:

1. The Process Is Effective at Reducing Levels of *E. coli* O157:H7

The USDA Agricultural Research Service's Meat Animal Research Center (MARC) conducted a study on the effectiveness of low-dose, low penetration e-beam irradiation in reducing levels of *E. coli* O157:H7 on chilled beef carcass surface cuts. (Arthur, Terrance M. and *et al.* 2005. Effects of Low-Dose, Low-Penetration Electron Beam Irradiation of Chilled Beef Carcass Surface Cuts on *Escherichia coli* O157:H7 and Meat Quality. *Journal of Food Protection, Vol. 68, No. 4 2005, Pages 666–672.)*

In the study, portions of beef cutaneous trunci muscle were selected to represent the carcass surface because the muscle, which covers portions of the beef plate and beef flank, is the outermost surface muscle and thus approximates the surface matrix of a beef carcass. Forty cutaneous trunci pieces were inoculated with *E. coli* O157:H7, twenty with a high concentration of 6 log cfu/cm^2 (high inoculation) and twenty with a low concentration of 3 log cfu/cm^2 (low inoculation). The forty samples were cut into equal portions for a total of eighty samples. One half of the high inoculated and low inoculated samples were treated with surface dosage of 1 kGy with approximately 15 mm of penetration. The remaining samples were not treated.

Results for direct cell count plating show that while the *E. coli* O157:H7 contamination of the untreated samples remained around the high inoculation level (7.2 logs after attachment, 6.6 logs at 48 hours and 5.9 logs at 120 hours) and the low inoculation level (3.9 logs after attachment, 2.9 logs after 48 hours, and 2.6 logs after 120 hours), *E. coli* O157:H7 was undetectable after 48 hours in irradiated samples that had been inoculated at the high level and was present at approximately 0.1 log after 120 hours. For the low inoculation level, the irradiation treated samples

were undetectable for *E. coli* O157:H7 after 48 and 120 hours. In addition to direct plating, researchers conducted enumeration of positive samples using the most probable number (MPN) technique. The results of the MPN analysis were similar to that from direct plating, indicating that the numbers of viable *E. coli* O157:H7 cells following irradiation were very low. There was no low-inoculation sample at 48 hours and only one low-inoculation sample at 120 hours that had a MPN value above the limit of detection (minimum level of detection was 0.036 CFU/cm^2). All of the high-inoculation samples were above the limit of detection.

These data appear to support the conclusion that a low dose (≤ 1.0 kGy surface dose), low penetration (20mm) surface e-beam irradiation process will produce a significant surface reduction of *E. coli* O157:H7 on chilled beef carcasses. FSIS solicits comment on whether this conclusion is correct, and on whether there are data available that would support a different conclusion.

2. The Process Does Not Have Any Affect on Quality or Appearance

The MARC's study also addressed effects of low dose, low penetration e-beam process on organoleptic properties of treated product. Spilt beef carcasses have thin external muscles that may be partially exposed from the carcass splitting process. During low dose e-beam irradiation of carcass sides, these muscles will receive various doses of radiation depending on their location and the extent of fat cover. In MARC's assessment of organoleptic impact, the flank steak was used as the model muscle because it is partially surface exposed; consistent in size, shape, and location; easy to access and remove; and possesses sufficient surface fat and surface layer molding to achieve variable penetration.

None of the flank steak sensory attributes (aroma intensity, off-aroma, tenderness, juiciness, flavor intensity, and off-flavor) were affected by any penetration treatment (10%–75% penetration). Three Hunter Color measurements (lightness, redness, and yellowness) were made in the MARC study, and all showed some treatment effects. However, the effects on lightness and yellowness were not linear with dose, and thus the investigators did not consider them to be meaningful treatment-related differences. The effects of treatment on redness values were linear. However, the researchers concluded that the magnitude of the effect was slight and would likely have no impact on consumer acceptance.

These data appear to support that a low dose, low penetration surface e-beam process does not have any affect on quality or appearance. FSIS asks for comment on whether the available data support this conclusion.

3. The Process Does Not Have an Effect on Shelf Life

A study of the effects of low dose, low-penetration e-beam surface exposure on the shelf life of beef was performed by Silliker Inc.

Twelve chilled beef plates from a commercial beef slaughter facility were removed from beef carcasses and transported to a commercial irradiation facility. Six beef plates were designated ''air-exposed,'' and three of these six were left untrimmed. Six beef plates were designated ''vac-pac,'' and all were trimmed. Six of these twelve were treated with low level (1 kGy), low penetration (15 mm) surface e-beam irradiation. The other six were left untreated as controls.

After the six beef plates were irradiated, the irradiated and control plates were randomly subdivided into four equal segments. Each segment was allocated into time slots of 1, 3, 6, and 9 days for air exposed, and 1, 10, 20, and 30 days for vac-pac. The following microbiological tests were performed at each measurement time: total aerobic plate count (APC) (35°C with aerobic atmosphere), hetero- and homo-lactic acid bacteria (LAB) (30°C with micro-aerobic atmosphere), total coliforms (35°C with aerobic atmosphere), and Biotype I *E. coli* (35–45°C with aerobic atmosphere). To provide a measure of oxidative rancidity, thiobarbituric acid (TBA) was analyzed throughout shelf life.

For APC, LAB, and total coliform counts of air-exposed beef after nine days, the irradiated samples were within 1.5 logs of the non-irradiated samples. For APC and LAB counts of vacuum packed beef after thirty days, the irradiated samples were within 1 log of the non-irradiated samples, while the total coliform counts were equivalent. The vacuum packed beef TBA values ranged from limited, tolerably oxidized to somewhat oxidized over 30 days of shelf life. The air exposed beef TBA values ranged from limited, tolerably oxidized at 2 days of shelf life to oxidized at 9 days of shelf life. All samples were below the range of rancidity.

Based on the results of this study, the initial antimicrobial effects of the treatment appear to have been minimal, and over the course of shelf life, the APC and LAB counts on the surface e-beam treated product increased to the point that quantitative levels nearly approximated the non-treated controls at the end of the storage period. In addition, one of the principal measurements of shelf life and product spoilage—rancidity—as measured by TBA indicated that the treated samples would turn rancid slightly before the non-treated controls. These data appear to demonstrate that the e-beam surface treatment of beef plates does not have a lasting effect on the product shelf-life.

Based on all of these data, a low dose, low penetration surface e-beam process appears not to have any affect on shelf-life. FSIS asks for comment on this tentative conclusion.

4. The Process Does Not Produce Significant Losses of Nutrients

A literature review and analysis on the effects of low dose, low-penetration e-beam irradiation on the levels of micro and macro nutrients was conducted by Dr. Donald W. Thayer, a retired USDA—ARS researcher (Thayer, Donald. 2004. Literature Review and Analysis of the Effects of Beef Carcass Surface Irradiation on Micro- and Macro-Nutrients).

Concerning macro-nutrients, Dr. Thayer found that there were no significant differences in the peroxide and iodine values of lipids following irradiation up to 10 kGy of the *m. longissimus dorsi* of beef. Also, there were no significant changes following irradiation in the malonaldehyde concentration in beef *m. longissimus dorsi* (Hampson, J.W., *et al.*, 1996. Effect of low dose gamma radiation on lipids in five different meats. Meat Science. 42:271–276). Concerning micro-nutrients, Dr. Thayer found that several authors studied the effects of sterilization doses of gamma irradiation on vitamins in ground beef at 1 kGy dose. According to Dr. Thayer's review, the water soluble vitamins in beef (niacin, vitamin B12, chorine, instill, and folacin) were ''unaltered.'' One water soluble and one fat soluble vitamin (thiamin and tocopherol) would likely be decreased. For these two vitamins, Dr. Thayer estimated, worse case, that the maximum net decrease in the U.S. diet would be only 0.021% for thiamin and 0.014% for tocopherol.

Dr. Thayer concluded that ''beef carcass surface, low dosage (1.0 kGy) electron beam irradiation will not produce a significant loss of either micro- or macro-nutrients from the U.S. diet.''

Based on these findings, it appears that a low dose, low penetration surface e-beam process does not have any significant effect on micro and macro

nutrients. FSIS asks for comment on this tentative conclusion.

Processing Aid

The AMI petition raised the issue of considering low dose, low penetration e-beam irradiation of the surface of beef carcasses to be a ''processing aid'' whose use would not need to be disclosed in the labeling of products derived from the carcasses that were irradiated. FSIS has consulted with FDA about this issue, and FDA has advised FSIS that, tentatively, it would not object to treating low dose, low penetration e-beam irradiation on the surface of chilled beef carcasses as a processing aid. FDA is still considering this issue and will likely consult further with FSIS.

Issues To Be Discussed at the Public Meeting

After considering the AMI petition, FSIS has tentatively concluded that there is merit to consider low dose (≤1.0 kGy) and low penetration (20mm) e-beam irradiation on the surface of chilled beef carcasses as a processing aid.

Data submitted showed that low dose, low penetration surface e-beam irradiation will produce a significant surface reduction of *E. coli* 0157:H7 on chilled beef carcasses. The e-beam treatment does not appear to have a lasting antimicrobial effect that would extend the shelf-life of the products, and it appears that there is no significant difference in color, odor, or taste between treated and untreated products. Relevant studies appear to support the assertion that the low dose, low penetration e-beam irradiation treatment would not produce any significant changes in the macro and micro nutrient content of the treated products. Further, the entire beef carcass is not irradiated, only the surface of the carcass.

Public Meeting and Comments

FSIS is seeking comment both at the public meeting and during the comment period on the following questions and those raised throughout this document:

- Is there any additional evidence to support or contradict the evidence presented in the AMI petition on the specific application of a low penetration of 20mm and low surface dosage of ≤1.0 kGy electron beam irradiation on the surfaces of chilled beef carcasses as a processing aid?
- Is there any evidence indicating that FSIS should consider the cumulative effects of the absorbed dose delivered in accordance with the AMI petition and any subsequent absorbed dose, such as a result of further irradiation of ground beef?
- Should FSIS consider requiring irradiation process controls if irradiation is considered a processing aid? If so, what would they be and what impact would they have on the low dose irradiation of chilled carcasses?
- Are there factors that FSIS has not considered? If so, what are they and what impact would they have?

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/*.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade and farm groups, consumer interest groups, allied health professionals and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*.

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done at Washington, DC on: September 2, 2008.

Alfred V. Almanza,

Administrator.

[FR Doc. E8–20653 Filed 9–5–08; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Recreation Resource Advisory Committees

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to renew the Recreation Resource Advisory Committees.

SUMMARY: The Secretary of Agriculture intends to renew five Forest Service Recreation Resource Advisory Committees (Recreation RACs) pursuant to Section 4 of the Federal Lands Recreation Enhancement Act passed into law as part of the 2005 Consolidated Appropriations Act (Pub. L. 108–447) on December 8, 2004. The Recreation RACs operate in the Pacific Northwest, Pacific Southwest, Eastern, and Southern Regions of the Forest Service and the State of Colorado, and provide recreation fee recommendations to both the Forest Service and the Bureau of Land Management (BLM) as appropriate. As required by the Federal Advisory Committee Act, charters for Federal advisory committees must be renewed every two years.

DATES: The current charter for the Recreation RACs expires September 28, 2008.

FOR FURTHER INFORMATION CONTACT: Julie Cox, National Recreation RAC Coordinator, USDA Forest Service, Pacific Northwest Region, 333 SW. 1st Avenue, Portland, OR 97208, (503) 808–2984.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The Federal Lands Recreation Enhancement Act (REA), signed in December 2004, directs the Secretary of Agriculture, the Secretary of the Interior, or both to establish Recreation RACs, or use existing advisory committees to perform the duties of Recreation RACs, in each State or region for Federal recreation lands and waters managed by the Forest Service or the BLM. These committees make recreation fee program recommendations on implementing or eliminating standard amenity fees; expanded amenity fees; and noncommercial, individual special recreation permit fees; expanding or limiting the recreation fee program; and fee-level changes.

The REA grants flexibility to Recreation RACs by stating that the Secretaries:

- May have as many additional Recreation RACs in a State or region as the Secretaries consider necessary;
- Shall not establish a Recreation RAC in a State if the Secretaries determine, in consultation with the Governor of the State, that sufficient interest does not exist to ensure that participation on the committee is balanced in terms of the points of view represented and the functions to be performed; or
- May use a resource advisory committee established pursuant to another provision of law and in accordance with that law.

The Forest Service and BLM elected to jointly use existing BLM RACs in the States of Arizona, Idaho, the Dakotas, Montana, Nevada, New Mexico, and Utah. The Forest Service also chartered new Recreation RACs for the Forest Service Pacific Northwest, Pacific Southwest, Eastern, and Southern Regions, and for the State of Colorado. The Forest Service is using an existing advisory board for the Black Hills National Forest in South Dakota. In addition, the Governors of three States—Alaska, Nebraska, and Wyoming—requested that their states be exempt from the Recreation RAC requirement, and the Secretary concurred with the exemptions.

Members were appointed to the Forest Service established Recreation RACs in February 2007 for three regions (Pacific Northwest, Eastern, and Southern), and July 2007 for one region (Pacific Southwest) and one State (State of Colorado).

The Secretaries have signed an Interagency Agreement that authorizes the Forest Service to using existing BLM RACs and the BLM to use Forest Service established Recreation RACs for the purposes stated in the REA.

Dated: September 2, 2008.

Boyd K. Rutherford,

Assistant Secretary for Administration.

[FR Doc. E8–20762 Filed 9–5–08; 8:45 am]

BILLING CODE 3410–11–P

BROADCASTING BOARD OF GOVERNORS

Sunshine Act Meeting

DATE AND TIME: Thursday, September 11, 2008, 2 p.m.–3 p.m.

PLACE: Cohen Building, Room 3321, 330 Independence Ave., SW., Washington, DC 20237.

CLOSED MEETING: The members of the Broadcasting Board of Governors (BBG) will meet in closed session to review and discuss a number of issues relating to U.S. Government-funded non-military international broadcasting. They will address internal procedural, budgetary, and personnel issues, as well as sensitive foreign policy issues relating to potential options in the U.S. international broadcasting field. This meeting is closed because if open it likely would either disclose matters that would be properly classified to be kept secret in the interest of foreign policy under the appropriate executive order (5 U.S.C. 552b.(c)(1)) or would disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. (5 U.S.C. 552b(c)(9)(B)). In addition, part of the discussion will relate solely to the internal personnel and organizational issues of the BBG or the International Broadcasting Bureau. (5 U.S.C. 552b.(c)(2) and (6))

FOR FURTHER INFORMATION CONTACT: Persons interested in obtaining more information should contact Timi Nickerson Kenealy at (202) 203–4545.

Dated: September 4, 2008.

Timi Nickerson Kenealy,

Acting Legal Counsel.

[FR Doc. E8–20840 Filed 9–4–08; 11:15 am]

BILLING CODE 8610–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a briefing meeting and a planning meeting of the Connecticut Advisory Committee to the Commission will convene at 11 a.m. on Monday, September, 22, 2008, in Room 1 C located in the Legislative Building, 210 Capitol Ave., in Hartford, Connecticut. The purpose of the briefing is to hear from local advocates on topical civil rights issues. After the briefing the Committee will plan future activities.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by October 22, 2008. The address is Eastern Regional Office, 624 9th St., NW., Washington, DC 20425. Persons wishing to e-mail their comments, or who desire additional information should contact Alfreda Greene, Secretary, at 202–376–7533 or by e-mail to: *agreene@usccr.gov.*

Hearing-impaired persons who will attend the meetings and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meetings.

Records generated from these meetings may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above e-mail or street address.

The meetings will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, September 3, 2008.

Christopher Byrnes,

Chief, Regional Programs Coordination Unit.

[FR Doc. E8–20744 Filed 9–5–08; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the District of Columbia Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that planning meetings of Subcommittees of the District of Columbia Advisory Committee to the Commission will convene at 12 p.m. on Tuesday, September 30, 2008, at the U.S. Commission on Civil Rights, 624 Ninth Street, NW., Conference Room 540, Washington, DC 20425. The Subcommittee on Immigration will convene at 12 p.m. and the Subcommittee on Voting Rights will convene at 1:30 p.m. The purpose of each meeting is to discuss possible topics to recommend to the District of Columbia SAC as a civil rights project.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by Monday, October 20, 2008. The address is Eastern Regional Office, 624 Ninth Street, NW., Suite 740, Washington, DC 20425. Persons who desire additional information should contact Alfreda Greene, Secretary, at 202–376–7533, or by e-mail: *agreene@usccr.gov.*

Hearing-impaired persons who will attend the meetings and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meetings.

Records generated from these meetings may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above e-mail or street address.

The meetings will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, September 3, 2008.

Christopher Byrnes,

Chief, Regional Programs Coordination Unit.

[FR Doc. E8–20742 Filed 9–5–08; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 0808181107–81109–01]

Effects of Foreign Policy-Based Export Controls

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Request for comments on foreign policy-based export controls.

SUMMARY: The Bureau of Industry and Security (BIS) is reviewing the foreign policy-based export controls in the Export Administration Regulations (EAR) to determine whether they should be modified, rescinded or extended. To help make these determinations, BIS is seeking comments on how existing foreign policy-based export controls have affected exporters and the general public. Additionally, BIS is particularly interested in comments regarding the Entity List (Supplement No. 4 to part 744 of the EAR), including on its usefulness and format, as well as on the specific entities listed and the licensing policies and requirements assigned to each.

DATES: Comments must be received by October 8, 2008.

ADDRESSES: Written comments may be sent by e-mail to *publiccomments@bis.doc.gov.* Include ''FPBEC'' in the subject line of the message. Written comments (three copies) may be submitted by mail or hand delivery to Jeffery Lynch, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For general questions regarding foreign policy-based export controls, Joan Roberts, Foreign Policy Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, telephone: (202) 482–4252, and for questions specific to the Entity List, Karen Nies-Vogel, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, telephone: (202) 482–3811. Copies of the current Annual Foreign Policy Report to the Congress are available at *http://www.bis.doc.gov/PoliciesAndRegulations/08ForPolControls/index.htm* and copies may also be requested by calling the Office of Nonproliferation and Treaty Compliance at the number listed above.

SUPPLEMENTARY INFORMATION: Foreign policy-based controls in the Export Administration Regulations (EAR) are implemented pursuant to section 6 of the Export Administration Act of 1979, as amended. The current foreign policy-based export controls maintained by the Bureau of Industry and Security (BIS) are set forth in the EAR, including in parts 742 (CCL Based Controls), 744 (End-User and End-Use Based Controls) and 746 (Embargoes and Special Country Controls). These controls apply to a range of countries, items, activities and persons, including: Certain general purpose microprocessors for ''military end-uses'' and ''military end-users'' (§ 744.17); significant items (SI): Hot section technology for the development, production, or overhaul of commercial aircraft engines, components, and systems (§ 742.14); encryption items (§§ 742.15 and 744.9); crime control and detection commodities (§ 742.7); specially designed implements of torture (§ 742.11); certain firearms included within the Inter-American Convention Against the Illicit Manufacturing of and Trafficking in Firearms, Ammunition, Explosives, and Other Related Materials (§ 742.17); regional stability items (§ 742.6); equipment and related technical data used in the design, development, production, or use of certain rocket systems and unmanned air vehicles (§§ 742.5 and 744.3); chemical precursors and biological agents, associated equipment, technical data, and software related to the production of chemical and biological agents (§§ 742.2 and 744.4) and various chemicals included in those controlled pursuant to the Chemical Weapons Convention (§ 742.18); nuclear propulsion (§ 744.5); aircraft and vessels (§ 744.7); communication intercepting devices (software and technology) (§ 742.13); embargoed countries (part 746); countries designated as supporters of acts of international terrorism (§§ 742.8, 742.9, 742.10, 742.19, 746.2, 746.4, 746.7, and 746.9); certain entities in Russia (§ 744.10); individual terrorists and terrorist organizations (§§ 744.12, 744.13 and 744.14); certain persons designated by Executive Order 13315 (''Blocking Property of the Former Iraqi Regime, Its Senior Officials and Their Family Members'') (§ 744.18); and certain sanctioned entities (§ 744.20). Attention is also given in this context to the controls on nuclear-related commodities and technology (§§ 742.3 and 744.2), which are, in part, implemented under section 309(c) of the Nuclear Non-Proliferation Act.

Under the provisions of section 6 of the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401–2420 (2000)) (EAA), export controls maintained for foreign policy purposes require annual extension. Section 6 of the EAA requires a report to Congress when foreign policy-based export controls are extended. The EAA expired on August 20, 2001. Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of July 23, 2008, 73 FR 43603 (July 25, 2008), continues the EAR and, to the extent permitted by law, the provisions of the EAA, in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706 (2000)). The Department of Commerce, insofar as appropriate, is following the provisions of section 6 by reviewing its foreign policy-based export controls, requesting public comments on such controls, and preparing a report to be submitted to Congress.

In January 2008, the Secretary of Commerce, on the recommendation of the Secretary of State, extended for one year all foreign policy-based export controls then in effect.

To assure maximum public participation in the review process, comments are solicited on the extension or revision of the existing foreign policy-based export controls for another year. Among the criteria considered in determining whether to continue or revise U.S. foreign policy-based export controls are the following:

1. The likelihood that such controls will achieve the intended foreign policy purpose, in light of other factors,

including the availability from other countries of the goods, software or technology proposed for such controls;

2. Whether the foreign policy objective of such controls can be achieved through negotiations or other alternative means;

3. The compatibility of the controls with the foreign policy objectives of the United States and with overall United States policy toward the country subject to the controls;

4. Whether the reaction of other countries to the extension of such controls is not likely to render the controls ineffective in achieving the intended foreign policy objective or be counterproductive to United States foreign policy interests;

5. The comparative benefits to U.S. foreign policy objectives versus the effect of the controls on the export performance of the United States, the competitive position of the United States in the international economy, the international reputation of the United States as a supplier of goods and technology; and

6. The ability of the United States to enforce the controls effectively.

BIS is particularly interested in receiving comments on the economic impact of proliferation controls. BIS is also interested in industry information relating to the following:

1. Information on the effect of foreign policy-based export controls on sales of U.S. products to third countries (i.e., those countries not targeted by sanctions), including the views of foreign purchasers or prospective customers regarding U.S. foreign policy-based export controls.

2. Information on controls maintained by U.S. trade partners. For example, to what extent do they have similar controls on goods and technology on a worldwide basis or to specific destinations?

3. Information on licensing policies or practices by our foreign trade partners that are similar to U.S. foreign policy-based export controls, including license review criteria, use of conditions, requirements for pre- and post-shipment verifications (preferably supported by examples of approvals, denials and foreign regulations).

4. Suggestions for revisions to foreign policy-based export controls that would bring them more into line with multilateral practice.

5. Comments or suggestions as to actions that would make multilateral controls more effective.

6. Information that illustrates the effect of foreign policy-based export controls on trade or acquisitions by intended targets of the controls.

7. Data or other information on the effect of foreign policy-based export controls on overall trade at the level of individual industrial sectors.

8. Suggestions as to how to measure the effect of foreign policy-based export controls on trade.

9. Information on the use of foreign policy-based export controls on targeted countries, entities, or individuals.

BIS is also interested in comments relating generally to the extension or revision of existing foreign policy-based export controls.

Entity List

The Entity List (Supplement No. 4 to Part 744 of the EAR) provides notice to the public that certain exports and reexports to parties identified on the Entity List require a license from BIS and that availability of License Exceptions in such transactions is limited. In connection with the annual review of all foreign policy-based export controls, BIS is particularly interested in public comments regarding the Entity List, including but not limited to those specific to the entities on the List and the licensing policies and requirements assigned to each of them, and on the Entity List's utility and suggestions for ways it might be improved through changes in format, organization or otherwise.

Parties submitting comments are asked to be as specific as possible. All comments received before the close of the comment period will be considered by BIS in reviewing the controls and developing the report to Congress and/or in implementing changes to the Entity List.

BIS will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. BIS will return such comments and materials to the persons submitting the comments and will not consider them in the development of a response. All information relating to the notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, BIS requires written comments. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying.

The Office of Administration, Bureau of Industry and Security, U.S. Department of Commerce, displays these public comments on BIS's Freedom of Information Act (FOIA) Web site at *http://www.bis.doc.gov/foia.* This office does not maintain a separate public inspection facility. If you have technical difficulties accessing this Web site, please call BIS's Office of Administration at (202) 482–0637 for assistance.

Dated: August 29, 2008.

Christopher R. Wall,

Assistant Secretary for Export Administration.

[FR Doc. E8–20672 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–892

Carbazole Violet Pigment 23 from the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on carbazole violet pigment 23 (CVP 23) from the People's Republic of China (PRC). The period of review (POR) is December 1, 2006, through November 30, 2007. We preliminarily determine that 11 companies have failed to cooperate by not acting to the best of their ability to comply with our requests for information and, as a result, should be assigned a rate based on adverse facts available (AFA). We are also rescinding this administrative review with respect to three companies. If these preliminary results are adopted in our final results of this review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of subject merchandise during the POR.

Interested parties are invited to comment on these preliminary results. We will issue the final results no later than 120 days from the date of publication of this notice.

EFFECTIVE DATE: September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Deborah Scott or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–2657 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2004, the Department published the antidumping duty order on CVP 23 from the PRC. *See Antidumping Duty Order: Carbazole Violet Pigment 23 From the People's Republic of China*, 69 FR 77987 (December 29, 2004). On December 3, 2007, the Department published *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 72 FR 67889 (December 3, 2007). On December 31, 2007, Nation Ford Chemical Company and Sun Chemical Corporation (collectively, petitioners) requested an administrative review of entries of subject merchandise made during the POR by 14 Chinese exporters, in accordance with 19 CFR 351.213(b)(1). The 14 exporters included in petitioners' request for review were: Aesthetic Colortech (Shanghai) Company, Limited (Aesthetic Colortech); Anhui Worldbest IE Company, Limited (Anhui Worldbest); Cidic Company, Limited (Cidic); Ganguink Company, Pigment Division (Ganguink); Goldlink Industries Company, Limited (Goldlink); Hunan Sunlogistics International Company, Limited (Hunan Sunlogistics); Hygeia–Chem (Shanghai) Company, Limited (Hygeia–Chem); Nantong Haidi Chemical Company, Limited (Nantong Chemical); Pudong Prime International Logistic Incorporated (Pudong Prime); Shanghai Rainbow Dyes Import and Export (Shanghai Rainbow); Sinocol Corporation, Limited (Sinocol); Tianjin Hanchem International Trading Company, Limited (Tianjin Hanchem); Trust Chem Company, Limited (Trust Chem); and Yangcheng Tiacheng Chemical Company, Limited (Yangcheng Chemical).

On January 28, 2008, the Department initiated an administrative review of these 14 companies. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 73 FR 4829 (January 28, 2008). On February 1, 2008, the Department issued a letter to interested parties announcing its intention to limit the number of respondents selected for review and to select respondents based on CBP data for U.S. imports of CVP 23 during the POR. On February 4, 2008, the Department requested that petitioners submit addresses for each of the companies included in their request for review; petitioners provided address information to the Department on that same date. On February 5, 2008, the Department released the letter regarding its respondent–selection methodology and the CBP import data to the 14 Chinese exporters and extended the deadline for parties to submit comments until February 12, 2008. For information related to the delivery of these letters, *see* the memorandum entitled ''Carbazole Violet Pigment 23 from the People's Republic of China: Delivery of Various Documents to Respondents in the 2006–2007 Administrative Review,'' dated August 27, 2008 (Delivery Tracking Memorandum) at Attachment 1. No interested parties submitted comments to the Department.

On February 25, 2008, because it was not feasible to examine all 14 exporters of the subject merchandise, for purposes of this administrative review, the Department selected the largest company by export volume, Goldlink, as a mandatory respondent in accordance with section 777A(c)(2) of the Tariff Act of 1930, as amended (the Act). *See* Memorandum from Blanche Ziv to Wendy J. Frankel, ''2006–2007 Antidumping Duty Administrative Review of Carbazole Violet Pigment 23 from the People's Republic of China: Selection of Respondents,'' dated February 25, 2008. On February 26, 2008, the Department issued an antidumping questionnaire to Goldlink. For information regarding the delivery of this questionnaire, *see* the Delivery Tracking Memorandum at Attachment 2. Goldlink did not respond to the Department's questionnaire.

On March 3, 2008, the Department sent separate rate applications/ certifications to the following 12 Chinese exporters of CVP 23: Aesthetic Colortech; Anhui Worldbest; Cidic; Ganguink; Goldlink; Hunan Sunlogistics; Nantong Chemical; Pudong Prime; Shanghai Rainbow; Sinocol; Tianjin Hanchem; and Trust Chem. On March 4, 2008, the Department sent separate rates applications/certifications to Hygeia–Chem and Yangcheng Chemical after petitioners provided more accurate addresses for these two exporters. For information regarding the delivery of the separate rate applications/ certifications, *see* the Delivery Tracking Memorandum at Attachment 3. The Department did not receive a response to the separate rate application/ certification from any of the 14 companies.

On April 18, 2008, the Department sent a second letter to each of the four companies that had been assigned a separate rate in a prior segment of this proceeding, namely, Goldlink, Nantong Chemical, Tianjin Hanchem, and Trust Chem. For information regarding the delivery of these letters, *see* the Delivery Tracking Memorandum at Attachment 4. In its letter to Goldlink, the Department stated that since Goldlink did not respond to the antidumping questionnaire, the Department may resort to the use of facts available with an adverse inference. The Department further stated that because Goldlink did not submit its response by the Department's deadline, Goldlink may not be eligible to receive a separate rate in this proceeding and thus would be considered part of the PRC entity and assigned the PRC–wide rate. The Department granted Goldlink until April 28, 2008, to provide an explanation as to why it did not submit a response to the questionnaire, and stated the Department would determine at that time whether an extension was warranted for Goldlink to submit its questionnaire response. In its April 18, 2008, letters to Nantong Chemical, Tianjin Hanchem, and Trust Chem, the Department declared that as each company did not provide a response to the Department's separate rate certification, these companies may not be eligible to receive a separate rate in this proceeding and thus would be considered part of the PRC entity and assigned the PRC–wide rate. The Department granted Nantong Chemical, Tianjin Hanchem, and Trust Chem until April 28, 2008, to provide an explanation as to why they were unable to submit a separate rate certification, and stated the Department would determine at that time whether an extension was warranted for each company to submit a separate rate certification. None of the four companies responded to the Department's April 18, 2008, letters by the established deadline.

On April 29, 2008, Tianjin Hanchem submitted a letter stating it did not make any sales or exports during the POR, and explaining it did not respond to the Department's separate rate application/ certification letter because it was not aware it needed to respond when it had no shipments to the United States. On May 7, 2008, Trust Chem filed a letter stating it had no shipments and no sales of CVP 23 during the POR.

On July 17, 2008, the Department sent another separate rate application/ certification to one company, Ganguink, because the Department found the separate rate application/certification sent to this company on March 3, 2008, had not been delivered. For information related to the delivery of this document, *see* the Delivery Tracking Memorandum at Attachment 5. The Department did not receive a response from Ganguink.

Period of Review

The POR is December December 1, 2006, through November 30, 2007.

Scope of the Order

The merchandise covered by this order is carbazole violet pigment 23 identified as Color Index No. 51319 and Chemical Abstract No. 6358–30–1, with the chemical name of diindolo [3,2–b:3',2'-m] triphenodioxazine, 8,18–dichloro–5, 15–diethy–5,15–dihydro-, and molecular formula of C34H22Cl2N4O2.[1] The subject merchandise includes the crude pigment in any form (*e.g.*, dry powder, paste, wet cake) and finished pigment in the form of presscake and dry color. Pigment dispersions in any form (*e.g.*, pigments dispersed in oleoresins, flammable solvents, water) are not included within the scope of this order. The merchandise subject to this order is classifiable under subheading 3204.17.9040 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Partial Rescission of Administrative Review

Section 351.213(d)(1) of the Department's regulations provides that the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review, or withdraws at a later date if the Department determines it is reasonable to extend the time limit for withdrawing the request.

In this case, the 90–day deadline to withdraw requests for an administrative review fell on April 28, 2008. However, on April 25, 2008, petitioners requested that the Department extend this deadline by ten days. Consequently, on April 28, 2008, the Department granted petitioners' request and extended the deadline until May 8, 2008. On May 8, 2008, petitioners submitted a letter withdrawing their request for an administrative review of Nantong Chemical, Tianjin Hanchem, and Trust Chem.

Thus, the petitioners timely withdrew their requests for an administrative review of Nantong Chemical, Tianjin Hanchem, and Trust Chem within the extended deadline. Because the petitioners were the only party to request administrative review of each of these companies, we are rescinding this administrative review with respect to Nantong Chemical, Tianjin Hanchem, and Trust Chem. Each of these three companies has a separate rate, and we will issue liquidation instructions for these companies' entries 15 days after publication of this notice.

Non–Market Economy Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as a non–market economy (NME) country. *See*, *e.g.*, *Polyethylene Retail Carrier Bags from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Review*, 72 FR 51588, 51590 (September 10, 2007), unchanged in *Polyethylene Retail Carrier Bags from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Partial Rescission of Review*, 73 FR 14216 (March 17, 2008). Pursuant to section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See*, *e.g.*, *Carbazole Violet Pigment 23 From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Rescission in Part*, 71 FR 65073, 65074 (November 7, 2006) unchanged in *Carbazole Violet Pigment 23 from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 72 FR 26589 (May 10, 2007). None of the parties to this proceeding have contested such treatment.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise in an NME country subject to review this single rate unless an exporter can demonstrate it is sufficiently independent so as to be entitled to a separate rate. To establish whether a company is sufficiently independent from government control of its export activities to be entitled to a separate company–specific rate, the Department analyzes each entity exporting the subject merchandise under a test arising from *Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China*, 56 FR 20588 at Comment 1 (May 6, 1991), as amplified by *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585, 22586–7 (May 2, 1994). The Department assigns separate rates in NME cases only if respondents can affirmatively demonstrate the absence of both *de jure* and *de facto* government control over export activities. The Department has preliminarily determined that none of the 11 respondents remaining in this administrative review qualify for a separate rate. For more information, *see* ''The PRC–Wide Entity'' section below.

The PRC–Wide Entity

Based on a timely request by petitioners, the Department originally initiated this administrative review with respect to 14 companies. As noted above, petitioners timely withdrew their request for review of three of these companies. Of the 11 companies remaining in this review, none of them responded to the Department's separate rate application/certification, including the mandatory respondent in this review, Goldlink, which also did not respond to the Department's antidumping questionnaire. *See* ''Background'' section above. Thus, Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical have not demonstrated the lack of both *de jure* and *de facto* government control over export activities. Therefore, we have preliminarily determined that none of these 11 exporters have demonstrated their eligibility for separate–rate status. As a result, the Department is treating these 11 companies as part of the PRC–wide entity. Because we have determined Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical are part of the PRC–wide entity, the PRC–wide entity is now under review.

Application of Facts Available

Section 776(a)(1) of the Act mandates that the Department use the facts available if necessary information is not available on the record of an antidumping proceeding. In addition, section 776(a)(2) of the Act provides that if an interested party or any other person: (A) withholds information that has been requested by the administering authority; (B) fails to provide such information by the deadlines for the submission of the information or in the

[1] The bracketed section of the product description, [3,2-b:3',2'-m], is not business proprietary information, but is part of the chemical nomenclature.

form and manner requested, subject to subsections (c)(1) and (e) of section 782 of the Act; (C) significantly impedes a proceeding under this title; or (D) provides such information but the information cannot be verified as provided in section 782(i) of the Act, the Department shall, subject to section 782(d) of the Act, use the facts otherwise available in reaching the applicable determination under this title.

Where the Department determines that a response to a request for information does not comply with the request, section 782(d) of the Act provides that the Department shall promptly inform the party submitting the response of the nature of the deficiency and shall, to the extent practicable, provide that party with an opportunity to remedy or explain the deficiency. Section 782(d) of the Act additionally states that if the party submits further information that is unsatisfactory or untimely, the administering authority may, subject to subsection (e), disregard all or part of the original and subsequent responses. Section 782(e) of the Act provides that the Department shall not decline to consider information that is submitted by an interested party and is necessary to the determination but does not meet all the applicable requirements established by the administering authority if: (1) the information is submitted by the deadline established for its submission; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability in providing the information and meeting the requirements established by the administering authority with respect to the information; and (5) the information can be used without undue difficulties.

The Department finds that the PRC–wide entity (including Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical) did not respond to our requests for information and that necessary information is not available on the record. Therefore, we have preliminarily determined that the use of facts otherwise available is warranted for the PRC–wide entity under sections 776(a)(1) and (2) of the Act.

As stated above in the ''Background'' section, on February 25, 2008, the Department selected Goldlink, the largest exporter of subject merchandise by volume, as a mandatory respondent. On February 26, 2008, the Department sent an antidumping questionnaire to Goldlink. On March 3, 2008, the Department also sent a separate rate application/certification to Goldlink. Goldlink did not respond to the questionnaire or the separate rate application/certification. On April 18, 2008, the Department sent a letter to Goldlink stating that since it did not respond to the antidumping questionnaire, the Department may resort to the use of facts available with an adverse inference. The Department also informed Goldlink that because it did not submit its response by the Department's deadline, Goldlink may not be eligible to receive a separate rate in this proceeding and thus would be considered part of the PRC entity and assigned the PRC–wide rate. In its April 18, 2008, letter, the Department granted Goldlink until April 28, 2008, to provide an explanation as to why it did not submit a response to the questionnaire and stated it would determine at that time whether an extension was warranted for Goldlink to submit its questionnaire response. Goldlink did not respond to the Department's April 18, 2008, letter. The Department has no information on the record for Goldlink with which to calculate a dumping margin or determine if it is eligible for a separate rate in this proceeding, and hence we preliminarily find that Goldlink has significantly impeded the proceeding by withholding information and failing to respond to the Department's request for information within the specified deadlines. Therefore, pursuant to sections 776(a)(1) and 776(a)(2)(A),(B), and (C) of the Act, the Department preliminarily determines that the application of facts available is appropriate. Because Goldlink did not respond to the Department's requests for information, sections 782(d) and (e) of the Act are not applicable.

Application of Adverse Facts Available

Section 776(b) of the Act provides that the Department may use an adverse inference in applying the facts otherwise available when a party has failed to cooperate by not acting to the best of its ability to comply with a request for information. Section 776(b) of the Act also authorizes the Department to use as AFA information derived from the petition, the final determination, a previous administrative review, or other information placed on the record.

Pursuant to section 776(b) of the Act, we find the PRC–wide entity, which includes Goldlink and the other companies remaining under review that did not provide separate rate applications or certifications (Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical), failed to cooperate by not acting to the best of its ability. As noted above, the PRC–wide entity did not provide the requested information. This information was in the sole possession of the respondents, and could not be obtained otherwise. Thus, because the PRC–wide entity refused to participate fully in this proceeding, we preliminarily determine that in selecting from among the facts otherwise available, an adverse inference is warranted for the PRC–wide entity pursuant to section 776(b) of the Act. By using an inference that is adverse to the interests of the PRC–wide entity, we ensure the companies that are part of the PRC–wide entity will not obtain a more favorable result by failing to cooperate than had they cooperated fully in this review.

Selection of Adverse Facts Available Rate

In deciding which facts to use as AFA, section 776(b) of the Act and 19 CFR 351.308(c) authorize the Department to rely on information derived from: (1) the petition; (2) a final determination in the investigation; (3) any previous review or determination; or (4) any information placed on the record. In reviews, the Department normally selects, as AFA, the highest rate on the record of any segment of the proceeding. *See, e.g., Freshwater Crawfish Tail Meat from the People's Republic of China; Notice of Final Results of Antidumping Duty Administrative Review*, 68 FR 19504, 19506 (April 21, 2003). The U.S. Court of International Trade (CIT) and the Court of Appeals for the Federal Circuit have consistently upheld the Department's practice in this regard. *See Rhone Poulenc, Inc. v. United States*, 899 F.2d 1185, 1190 (Fed. Circ. 1990) (*Rhone Poulenc*); *NSK Ltd. v. United States*, 346 F. Supp. 2d 1312, 1335 (CIT 2004) (upholding a 73.55 percent total AFA rate, the highest available dumping margin from a different respondent in a less–than-fair–value investigation); *see also Kompass Food Trading Int'l v. United States*, 24 CIT 678, 683–84 (2000) (upholding a 51.16 percent total AFA rate, the highest available dumping margin from a different, fully cooperative respondent); and *Shanghai Taoen International Trading Co., Ltd. v. United States*, 360 F. Supp. 2d 1339, 1348 (CIT 2005) (upholding a 223.01 percent total AFA rate, the highest

available dumping margin from a different respondent in a previous administrative review).

The Department's practice when selecting an adverse rate from among the possible sources of information is to ensure that the margin is ''sufficiently adverse so as to effectuate the statutory purposes of the adverse facts available rule to induce respondents to provide the Department with complete and accurate information in a timely manner.'' *See Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors from Taiwan*, 63 FR 8909, 8932 (February 23, 1998). The Department's practice also ensures ''that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See* Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–316, vol. 1 (1994) (SAA) at 870; *see also Notice of Final Determination of Sales at Less than Fair Value: Certain Frozen and Canned Warmwater Shrimp From Brazil*, 69 FR 76910, 76912 (December 23, 2004). In choosing the appropriate balance between providing respondents with an incentive to respond accurately and imposing a rate that is reasonably related to the respondent's prior commercial activity, selecting the highest prior margin ''reflects a common sense inference that the highest prior margin is the most probative evidence of current margins, because, if it were not so, the importer, knowing of the rule, would have produced current information showing the margin to be less.'' *See Rhone Poulenc*, 899 F.2d at 1190.

Consistent with the statute, court precedent, and its normal practice, the Department has preliminarily assigned the rate of 241.32 percent, the highest rate determined in any segment of this proceeding, to the PRC–wide entity, which includes Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical, as AFA. *See* Final Results of Redetermination Pursuant to United States Court of International Trade Remand Order, *Goldlink Industries Co., Ltd. v. United States*, 431 F. Supp. 2d 1323 (CIT May 4, 2006), affirmed by the CIT on December 8, 2006 (*CVP 23 from the PRC – Remand on Final Determination*); see also Carbazole Violet Pigment 23 from the People's Republic of China: Notice of Amended Final Determination in Accordance with Court Decision, 72 FR 15101 (March 30, 2007) (*CVP 23 from the PRC – Amended Final Determination*). As discussed further below, this rate has been corroborated.

Corroboration of Secondary Information Used as Adverse Facts Available

Section 776(c) of the Act provides that, where the Department selects from among the facts otherwise available and relies on ''secondary information,'' the Department shall, to the extent practicable, corroborate that information from independent sources reasonably at the Department's disposal. Secondary information is described in the SAA as ''{i}nformation derived from the petition that gave rise to the investigation or review, the final determination covering the subject merchandise, or any previous review under section 751 concerning the subject merchandise.'' *See* SAA at 870. The SAA states that ''corroborate'' means to determine that the information used has probative value. *Id.* The Department has determined that to have probative value, information must be reliable and relevant. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings Four Inches or Less in Outside Diameter, and Components Thereof, from Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews*, 61 FR 57391, 57392 (November 6, 1996), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part*, 62 FR 11825 (March 13, 1997). The SAA also states that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation or review. *See* SAA at 870; *see also Notice of Preliminary Determination of Sales at Less Than Fair Value: High and Ultra–High Voltage Ceramic Station Post Insulators from Japan*, 68 FR 35627 (June 16, 2003), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: High and Ultra–High Voltage Ceramic Station Post Insulators from Japan*, 68 FR 62560 (November 5, 2003); and *Notice of Final Determination of Sales at Less Than Fair Value: Live Swine From Canada*, 70 FR 12181, 12183 (March 11, 2005).

To be considered corroborated, information must be found to be both reliable and relevant. Unlike other types of information, such as input costs or selling expenses, there are no independent sources for calculated dumping margins. The only sources for calculated margins are administrative determinations. The AFA rate we are applying for the current review was calculated pursuant to a remand order from the CIT with respect to the original investigation of CVP 23 from the PRC. *See CVP 23 from the PRC – Remand on Final Determination* and *CVP 23 from the PRC – Amended Final Determination*. Furthermore, no information has been presented in the current review that calls into question the reliability of this information. Thus, the Department finds that the information is reliable.

With respect to the relevance aspect of corroboration, the Department will consider information reasonably at its disposal to determine whether a margin continues to have relevance. Where circumstances indicate the selected margin is not appropriate as AFA, the Department will disregard the margin and determine an appropriate margin. *See, e.g., Fresh Cut Flowers from Mexico: Final Results of Antidumping Administrative Review*, 61 FR 6812, 6814 (February 22, 1996). Similarly, the Department does not apply a margin that has been discredited. *See D & L Supply Co. v. United States*, 113 F. 3d 1220, 1221 (Fed. Cir. 1997) (the Department will not use a margin that has been judicially invalidated.) The AFA rate we are applying for the instant review was calculated based on export price information from the petition, as well as on production data of a respondent in the investigation and the most appropriate surrogate value information available to the Department. Furthermore, the calculation of this margin was subject to comment from interested parties in the proceeding. *See CVP 23 from the PRC – Remand on Final Determination* and *CVP 23 from the PRC – Amended Final Determination*. Moreover, as there is no information on the record of this review that demonstrates this rate is not appropriately used as AFA, we determine this rate has relevance.

As the AFA rate is both reliable and relevant, we find it has probative value. As a result, the Department preliminarily determines that the AFA margin (*i.e.*, the PRC–wide rate from *CVP 23 from the PRC – Remand on Final Determination* and *CVP 23 from the PRC – Amended Final Determination*) is corroborated for the purposes of this administrative review

and may reasonably be applied to the PRC–wide entity, which includes Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical. Because these are the preliminary results of review, the Department will consider all margins on the record at the time of the final results of review for the purpose of determining the most appropriate final margin for Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical. *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Solid Fertilizer Grade Ammonium Nitrate From the Russian Federation*, 65 FR 1139 (January 7, 2000), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value; Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation*, 65 FR 42669 (July 11, 2000).

Preliminary Results of Review

We preliminarily determine that the following antidumping duty margins exist for the period December 1, 2006, through November 30, 2007:

Exporter/Manufacturer	Margin (percent)
PRC–Wide Rate (including Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical)	241.32

Schedule for Final Results of Review

Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review. *See* 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing the case briefs. *See* 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument. Parties are also encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

Interested parties who wish to request a hearing or to participate if one is requested must submit a written request to the Assistant Secretary for Import Administration within 30 days of publication of these preliminary results. *See* 19 CFR 351.310(c). Requests should contain the following information: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the case and rebuttal briefs. Any hearing, if requested, will be held 37 days after the date of publication, or the first business day thereafter, unless the Department alters the date pursuant to 19 CFR 351.310(d)(1).

The Department intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. If these preliminary results are adopted in our final results of review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries.

Cash Deposit Requirements

The following cash–deposit requirements will be effective upon publication of the final results for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for PRC exporters who received a separate rate in a prior segment of the proceeding (*i.e.*, Nantong Chemical, Tianjin Hanchem, and Trust Chem) will continue to be the rate assigned in that segment of the proceeding; (2) for all other PRC exporters of subject merchandise which have not been found to be entitled to a separate rate (including Aesthetic Colortech, Anhui Worldbest, Cidic, Ganguink, Goldlink, Hunan Sunlogistics, Hygeia–Chem, Pudong Prime, Shanghai Rainbow, Sinocol, and Yangcheng Chemical), the cash–deposit rate will be the PRC–wide rate of 241.32 percent; (3) for all non–PRC exporters of subject merchandise, the cash–deposit rate will be the rate applicable to the PRC supplier of that exporter.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 2, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–20750 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–533–838

Carbazole Violet Pigment 23 from India: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from an interested party, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on carbazole violet pigment 23 from India. The review covers two manufacturers/exporters, Alpanil Industries and Pidilite Industries Limited. The period of review is December 1, 2006, through November 30, 2007. We have preliminarily determined that Alpanil Industries and Pidilite Industries Limited made sales below normal value. We invite interested parties to comment on these preliminary results. Parties who submit comments in this review are requested to submit with each argument a statement of each issue and a brief summary of the argument.

EFFECTIVE DATE: September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Hermes Pinilla, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–5760 or (202) 482–3477, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2004, we published in the **Federal Register** the antidumping duty order on carbazole violet pigment 23 (CVP 23) from India. See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Carbazole Violet Pigment 23 From India*, 69 FR 77988 (December 29, 2004) (*Antidumping Duty Order*). On December 3, 2007, we published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on CVP 23 from India. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 72 FR 67889 (December 3, 2007). On December 31, 2007, pursuant to section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), Nation Ford Chemical Company and Sun Chemical Corporation, the petitioners in this proceeding, requested an administrative review of the antidumping duty order on CVP 23 from India produced and/or exported by Alpanil Industries (Alpanil) and Pidilite Industries Limited (Pidilite). On January 28, 2008, in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we published a notice of initiation of administrative review of this order. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 73 FR 4829 (January 28, 2008). The administrative review covers the period December 1, 2006, through November 30, 2007. We are conducting this administrative review in accordance with section 751 of the Act.

Scope of the Order

The merchandise subject to the order is CVP 23 identified as Color Index No. 51319 and Chemical Abstract No. 6358–30–1, with the chemical name of diindolo [3,2–b:3 ,2 -m][1] triphenodioxazine, 8,18–dichloro–5, 15–diethyl–5, 15–dihydro-, and molecular formula of $C_{34}H_{22}Cl_2N_4O_2$. The subject merchandise includes the crude pigment in any form (*e.g.*, dry powder, paste, wet cake) and finished pigment in the form of presscake and dry color. Pigment dispersions in any form (*e.g.*, pigment dispersed in oleoresins, flammable solvents, water) are not included within the scope of the order. The merchandise subject to the order is classifiable under subheading 3204.17.90.40 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Use of Adverse Facts Available

For the reasons discussed below, we determine that the use of adverse facts available is appropriate for the preliminary results with respect to Alpanil and Pidilite.

A. Use of Facts Available

Section 776(a)(2) of the Act provides that, if an interested party withholds information requested by the administering authority, fails to provide such information by the deadlines for submission of the information and in the form or manner requested, significantly impedes a proceeding under this title, or provides such information but the information cannot be verified as provided in section 782(i) of the Act, the administering authority shall use facts otherwise available in reaching the applicable determination.

On February 21, 2008, the Department transmitted its questionnaire to Alpanil and Pidilite *via* Federal Express. We confirmed that Alpanil and Pidilite signed for and received the questionnaire on February 25, 2008. The due date for the questionnaire response was March 31, 2008, for both respondents. On March 27, 2008, we received a request from Pidilite for an extension of the due date for the questionnaire response. We granted Pidilite's extension request in part and extended the due date for the questionnaire response to April 21, 2008. Although Pidilite received the letter granting the extension on April 4, 2008, it did not file its response by the due date.

On April 4, 2008, we received a request from Alpanil for an extension of the due date for the questionnaire response. Because Alpanil filed an extension request in an untimely manner, we did not grant Alpanil's request for the extension of the due date for the questionnaire response.

Because Alpanil and Pidilite did not provide their responses to the Department's questionnaire, Alpanil and Pidilite failed to provide any information to the Department within the meaning of section 776(a)(2) of the Act. As a result, the Department is unable to calculate the margins for Alpanil and Pidilite and, therefore, must rely entirely on facts available.

B. Application of Adverse Inferences for Facts Available

Section 776(b) of the Act provides that, if the Department finds that an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information, the Department may use an inference adverse to the interests of that party in selecting the facts otherwise available. In addition, the Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Rep. 103–316, Vol. 1, 103d Cong. (1994) (SAA), establishes that the Department may employ an adverse inference ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' See SAA at 870. It also instructs the Department to consider, in employing adverse inferences, ''the extent to which a party may benefit from its own lack of cooperation.'' *Id.*

Furthermore, ''affirmative evidence of bad faith on the part of a respondent is not required before the Department may make an adverse inference.'' See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27340 (May 19, 1997). We find that, by failing completely to respond to our questionnaire, *i.e.*, withholding requested information, Alpanil and Pidilite failed to cooperate to the best of their abilities. Therefore, we find it appropriate to use an inference that is adverse to these companies' interests in selecting from among the facts otherwise available. By doing so, we ensure that these companies will not obtain a more favorable rate by failing to cooperate than had they cooperated fully.

C. Selection of Information Used as Facts Available

Where the Department applies an adverse facts–available rate because a respondent failed to cooperate by not acting to the best of its ability to comply with a request for information, section 776(b) of the Act authorizes the Department to rely on information derived from the petition, a final determination, a previous administrative review, or other information placed on the record. See also 19 CFR 351.308(c) and the SAA at 870. The petition rate is 147.59 percent. See the November 21, 2003, petition for initiation of an antidumping duty investigation on CVP 23 from India, *et al.*, at 21, unchanged in the December 3, 2003, amendment to the petition. Because we were not able to corroborate the petition rate based on the results of

[1] The bracketed section of the product description, [3,2-b:3 ,2 -m], is not business-proprietary information. In this case, the brackets are simply part of the chemical nomenclature. See *Antidumping Duty Order.*

examination in previous segments of the proceeding, we have selected 66.59 percent as the adverse facts–available dumping margin. This is the highest calculated margin for a company in this proceeding; we calculated this margin for Pidilite in the investigation. See *Antidumping Duty Order*, 69 FR at 77989. This rate is sufficiently high as to reasonably ensure that Alpanil and Pidilite do not obtain a more favorable result by failing to cooperate.

Section 776(c) of the Act provides that, when the Department relies on secondary information as facts available, it must corroborate, to the extent practicable, that information from independent sources that are reasonably at its disposal. The SAA clarifies that ''corroborate'' means that the Department will satisfy itself that the secondary information to be used has probative value. See SAA at 870. The SAA also states that independent sources used to corroborate may include, for example, published price lists, official import statistics, and customs data as well as information obtained from interested parties during the particular proceeding. *Id.*

To corroborate secondary information, to the extent practicable, the Department normally examines the reliability and relevance of the information to be used. Unlike other types of information such as input costs or selling expenses, however, there are no independent sources for calculated dumping margins. The only source for margins is administrative determinations. Thus, with respect to an administrative review, if the Department chooses as facts available a calculated dumping margin from a prior segment of the proceeding, it is not necessary to question the reliability of the margin for that time period. See *Antifriction Bearings and Parts Thereof from France, et al.: Preliminary Results of Antidumping Duty Administrative Reviews, Partial Rescission of Administrative Reviews, Notice of Intent to Rescind Administrative Reviews, and Notice of Intent to Revoke Order in Part*, 69 FR 5949, 5953 (February 9, 2004), unchanged in *Antifriction Bearings and Parts Thereof from France, et al.: Final Results of Antidumping Duty Administrative Reviews, Rescission of Administrative Reviews in Part, and Determination To Revoke Order in Part*, 69 FR 55574, 55576–77 (September 15, 2004).

With respect to the relevance aspect of corroboration, however, the Department will consider information reasonably at its disposal to determine whether a margin continues to have relevance. Where circumstances indicate that the selected margin is not appropriate as adverse facts available, the Department will disregard the margin and determine an appropriate margin. For example, in *Fresh Cut Flowers from Mexico; Final Results of Antidumping Duty Administrative Review*, 61 FR 6812, 6814 (Feb. 22, 1996), the Department disregarded the highest margin in that case as adverse best information available (the predecessor to facts available) because the margin was based on another company's uncharacteristic business expense resulting in an unusually high margin. Similarly, the Department does not apply a margin that has been discredited or judicially invalidated. See *D & L Supply Co. v. United States*, 113 F.3d 1220, 1221 (CAFC 1997).

None of these unusual circumstances is present here. Moreover, there is no information on the record of this review that demonstrates that 66.59 percent is not an appropriate adverse facts–available rate for Alpanil and Pidilite. Therefore, we consider the dumping margin of 66.59 percent, which is a margin percentage we determined in the less–than-fair–value investigation, relevant for use as adverse facts available for this review. Because we are making an adverse inference with regard to Alpanil and Pidilite, we find that the rate of 66.59 percent is a reasonable indication of the margins that Alpanil and Pidilite would have received on their U.S. transactions had they responded to our request for information. We find that use of the rate of 66.59 percent as adverse facts available is sufficiently high to ensure that Alpanil and Pidilite do not benefit from failing to cooperate in our review by refusing to respond to our questionnaire. See *Certain Cut–to-Length Carbon–Quality Steel Plate Products from the Republic of Korea: Final Results of Antidumping Duty Administrative Review and Rescission of Administrative Review in Part*, 73 FR 15132, 15133 (March 21, 2008).

Adjustment for Export Subsidies

For Pidilite in the original investigation, we subtracted the portion of the countervailing duty rate attributable to export subsidies (17.02 percent) from the final dumping margin of 66.59 percent in order to calculate the cash–deposit rate of 49.57 percent. See *Antidumping Duty Order*. Since the publication of the *Antidumping Duty Order* we have not conducted an administrative review of the countervailing duty order on CVP 23 from India. See *Carbazole Violet Pigment 23 from India: Notice of Rescission of Countervailing Duty Administrative Review*, 72 FR 15113 (March 30, 2007), and *Carbazole Violet Pigment 23 from India: Rescission of Countervailing Duty Administrative Review*, 73 FR 44704 (July 31, 2008). Therefore, the portion of the countervailing duty rate attributable to export subsidies currently in effect for Pidilite is 17.02 percent. Further, imports from both Alpanil and Pidilite during the review period were subject to countervailing duties to offset export subsidies of 17.02 percent or more. Because the adverse facts–available rate we selected for this review is the margin we calculated for Pidilite in the investigation, we have adjusted the dumping margin to ensure that, in accordance with section 772(c)(1)(C) of the Act, we do not collect duties attributable to export subsidies twice.

Preliminary Results of the Review

As a result of our review, we preliminarily determine that the weighted–average dumping margins for CVP 23 from India for the period December 1, 2006, through November 30, 2007, are as follows:

Company	Margin (percent)	Rate Adjusted for Export Subsidies
Alpanil	66.59	49.57
Pidilite	66.59	49.57

Comments

We will disclose the draft liquidation instructions to parties to this review within five days of the date of publication of this notice. Case briefs from interested parties may be submitted not later than 30 days after the date of publication of this notice of preliminary results of review. Rebuttal briefs from interested parties, limited to the issues raised in the case briefs, may be submitted not later than five days after the time limit for filing the case briefs or comments.

Any interested party may request a hearing within 30 days of the date of publication of this notice. Interested parties who wish to request a hearing, or to participate in a hearing if a hearing is requested, must submit a written request to the Assistant Secretary for Import Administration within 30 days of the date of publication of this notice. Requests should contain the following: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed.

Issues raised in the hearing will be limited to those raised in the case and rebuttal briefs. Any hearing, if requested, will be held two days after the scheduled date for submission of rebuttal briefs. Parties who submit case briefs or rebuttal briefs in this review are requested to submit with each argument a statement of the issue, a summary of the arguments not exceeding five pages, and a table of statutes, regulations, and cases cited.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any such written briefs or at the hearing, if held, not later than 120 days after the date of publication of this notice.

Assessment Rates

The Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. We intend to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of review. We will instruct CBP to assess the antidumping liability for all shipments of CVP 23 from India produced and/or exported by Alpanil or Pidilite and entered, or withdrawn from warehouse, for consumption during the period of review. We will instruct CBP to assess antidumping duties at the adjusted rate of 49.57 percent if CBP has collected the appropriate countervailing duties on the same entry. We will instruct CBP to assess antidumping duties at the unadjusted rate of 66.59 percent if the appropriate countervailing duties are not collected by CBP.

Cash–Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of CVP 23 from India entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash–deposit rates for Alpanil and Pidilite will be the rates established in the final results of this review; (2) if the exporter is not a firm covered in this review, a previous review, or the less–than-fair–value investigation but the manufacturer is, the cash–deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (3) if neither the exporter nor the manufacturer has its own rate, the cash–deposit rate will be 27.48 percent, the all–others rate published in *Antidumping Duty Order*, 69 FR at 77989. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importer

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 2, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–20752 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–827)

Certain Cased Pencils from the People's Republic of China: Notice of Correction of Extension of Time Limit for Preliminary Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Alexander Montoro at (202) 482–0238 or Shane Subler at (202) 482–0189; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 25, 2008, the Department published a notice of extension of the time limit for the preliminary results of the antidumping duty review on certain cased pencils from the People's Republic of China. *See Certain Cased Pencils from the People's Republic of China: Extension of Time Limits for Preliminary Results of the Antidumping Duty Administrative Review,* 73 FR 49993 (August 25, 2008) (Extension Notice). We identified an error in the published version of the notice. Specifically, in the Extension Notice, the case number was incorrectly listed as C-570-827. The correct case number is A-570-827. This notice serves to correct the case number listed in the Extension Notice.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 2, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–20749 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Preliminary Results of the New Shipper Review and Fourth Antidumping Duty Administrative Review and Partial Rescission of the Fourth Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is conducting an administrative review of the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam (''Vietnam''). *See Notice of Antidumping Duty Order: Certain Frozen Fish Fillets From the Socialist Republic of Vietnam,* 68 FR 47909 (August 12, 2003) (''Order''). We preliminarily find that QVD Food Company Ltd. (''QVD'') and Binh An Seafood Joint Stock Co. (''Binh An'') did not sell subject merchandise at less than normal value (''NV'') during the period of review (''POR''), August 1, 2006, through July 31, 2007.

DATES: *Effective Date:* September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Alan Ray (QVD) and Matthew Renkey

(Binh An), Office 9, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–5403 and (202) 482–2312, respectively.

SUPPLEMENTARY INFORMATION:

Case History

On August 2, 2007, the Department published a notice of an opportunity to request an administrative review of the order. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 72 FR 42383 (August 2, 2007). By August 31, 2007, the Department received review requests for 32 companies from Petitioners [1] and certain individual companies. In addition, pursuant to 19 CFR 351.214(c), the Department also received a new shipper review request from Binh An.

On September 25, 2007, the Department initiated an antidumping duty administrative review on frozen fish fillets from Vietnam covering 32 companies. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 72 FR 54428 (September 25, 2007). On October 9, 2007, the Department initiated the new shipper review for Binh An. *See Notice of Initiation of Antidumping Duty Administrative Reviews: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 72 FR 57296 (October 9, 2007).[2] On March 3, 2008, the Department extended the deadline for the preliminary results of this review by 120 days, to September 2, 2008. *See Notice of Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative and Partial Rescission of Administrative Review: Certain Frozen Fish Fillets from Vietnam (''Extension and Partial Rescission Notice''),* 73 FR 11391 (March 3, 2008).

On October 12, 2007, the Department issued a letter to all interested parties informing them of its decision to select QVD and Vinh Hoan Co., Ltd. (''Vinh Hoan''), the two largest exporters of subject merchandise during the POR, as mandatory respondents based on Customs and Border Protection (''CBP'') import data. *See* Memorandum to the File from Catherine Bertrand, Senior Case Analyst Through Alex Villanueva, Program Manager, Respondent Selection Memorandum (''Respondent Selection Memo''), dated October 11, 2007.

Between November 1, 2007, and August 25, 2008, QVD submitted responses to the original sections A, C, and D questionnaires and supplemental sections A, C, and D questionnaires. Between November 11, 2007, and August 15, 2008, Binh An submitted responses to the original sections A, C, and D questionnaires and supplemental sections A, C, and D questionnaires. Vinh Hoan also submitted questionnaire responses, as indicated below; however, the administrative review for Vinh Hoan was rescinded. On August 22, 2008, Petitioners submitted comments regarding the preliminary results with respect to QVD and Binh An.

On March 3, 2008, the Department extended the preliminary results of administrative review and rescinded the administrative with respect to 25 companies, including Vinh Hoan, because all requesting parties for those companies timely withdrew their requests for review. *See Extension and Partial Rescission Notice.* Therefore, seven companies remain in this administrative review: An Xuyen Company Ltd. (''An Xuyen''), Lian Heng Trading Co., Ltd (''Lian Heng''), QVD Food Company, Ltd. (''QVD''), QVD Dong Thap Food Co., Ltd. (''QVD DT''), Thuan Hung Co., Ltd. (''Thuan Hung''), An Giang Fisheries Import and Export Joint Stock Company (''Agifish'' or ''AnGiang Fisheries Import and Export''); Anvifish Co., Ltd. (''Anvifish'').

An Xuyen/Vietnam-Wide Entity

As discussed above, in this administrative review we limited the selection of respondents using CBP import data. *See* Respondent Selection Memo at 3. In this case, we sent companies who were not selected the separate rates application and certification. See Letter to All Interested Parties, dated October 17, 2007. An Xuyen did not apply for a separate rate in this administrative review. Therefore, An Xuyen will continue to be part of the Vietnam-wide entity. Because the Department determines preliminarily that there were exports of merchandise under review from Vietnam producers/exporters that did not demonstrate their eligibility for separate-rate status, the Vietnam-wide entity is now under review.

Preliminary Partial Rescission

Lian Heng

On October 22, 2007, Lian Heng stated that it made no exports of subject merchandise during the POR. Our examination of shipment data from CBP for Lian Heng confirmed that there were no entries of subject merchandise from it during the POR. Therefore, because the record indicates that Lian Heng did not sell subject merchandise to the United States during the POR, we are preliminarily rescinding the administrative review for Lian Heng. *See* 19 CFR 351.213(d)(3).

QVD, QVD DT and Thuan Hung

On November 1, 2007, we received a questionnaire response from QVD indicating that QVD, QVD DT and Thuan Hung had export licenses during the POR, but that only QVD exported subject merchandise to the United States during the POR. *See* QVD's Questionnaire Response at 5. QVD, QVD DT and Thuan Hung provided a joint response to the separate rates section of the Department's questionnaires. Our examination of shipment data from CBP for QVD DT and Thuan Hung confirmed that there were no entries of subject merchandise from these entities during the POR. However, because QVD, QVD DT and Thuan Hung will continue to be treated as a single entity (see ''Affiliations'' section below), we will not rescind the review for QVD DT and Thuan Hung, because a component of the QVD Single Entity had entries of subject merchandise during the POR and remains subject to the administrative review.

Agifish & Anvifish

On November 30, 2007, Agifish submitted a separate rate certification. On December 11, 2007, Anvifish submitted a separate rate application. We also examined the CBP data placed on the record and confirmed that Agifish and Anvifish had entries of subject merchandise during the POR.

Separate Rates

A designation as a non-market economy (''NME'') remains in effect until it is revoked by the Department. *See* section 771(18)(C) of the Tariff Act of 1930, as amended (''the Act''). Accordingly, there is a rebuttable presumption that all companies within

[1] The Catfish Famers of America and individual U.S. catfish processors, America's Catch, Consolidated Catfish Companies, LLC dba Country Select Catfish, Delta Pride Catfish, Inc., Harvest Select Catfish, Inc., Heartland Catfish Company, Pride of the Pond, Simmons Farm Raised Catfish, Inc., and Southern Pride Catfish Company LLC (''Petitioners'').

[2] The Department also initiated a new shipper review on October 9, 2007, for Southern Fishery Industries Company, Ltd. (''South Vina''). However, unlike Binh An, South Vina did not agree to aligning its new shipper review with the concurrent administrative review and therefore, the preliminary results for South Vina were issued on July 22, 2008. *See Notice of Preliminary Rescission of New Shipper Review: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 73 FR 43689 (July 28, 2008).

Vietnam are subject to government control and, thus, should be assessed a single antidumping duty rate. It is the Department's standard policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, the Department analyzes each exporting entity in an NME country under the test established in the *Final Determination of Sales at Less than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''Sparklers''), as amplified by the *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''Silicon Carbide'').

A. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; and (2) any legislative enactments decentralizing control of companies.

Although the Department has previously assigned a separate rate to all of the companies eligible for a separate rate in the instant proceeding, it is the Department's policy to evaluate separate rates questionnaire responses each time a respondent makes a separate rates claim, regardless of whether the respondent received a separate rate in the past. *See Manganese Metal from the People's Republic of China, Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 63 FR 12440 (March 13, 1998).

In this review, Agifish, Anvifish, QVD, and Binh An [3] submitted complete responses to the separate rates certification and application. The evidence submitted by these companies includes government laws and regulations on corporate ownership, business licenses, and narrative information regarding the companies' operations and selection of management. The evidence provided by these companies supports a finding of a *de jure* absence of government control over their export activities, based on: (1) an absence of restrictive stipulations associated with the exporter's business license; and (2) the legal authority on the record decentralizing control over the respondents.

B. Absence of De Facto Control

The absence of *de facto* government control over exports is based on whether the respondent: (1) Sets its own export prices independent of the government and other exporters; (2) retains the proceeds from its export sales and makes independent decisions regarding the disposition of profits or financing of losses; (3) has the authority to negotiate and sign contracts and other agreements; and (4) has autonomy from the government regarding the selection of management. *See Silicon Carbide,* 59 FR at 22587; *Sparklers,* 56 FR at 20589; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

In this review, Agifish, Anvifish, QVD, and Binh An submitted evidence indicating an absence of *de facto* government control over their export activities. Specifically, this evidence indicates that: (1) Each company sets its own export prices independent of the government and without the approval of a government authority; (2) each company retains the proceeds from its sales and makes independent decisions regarding the disposition of profits or financing of losses; (3) each company has a general manager, branch manager or division manager with the authority to negotiate and bind the company in an agreement; (4) the general managers are selected by the board of directors or company employees, and the general managers appoint the deputy managers and the manager of each department; and (5) there is no restriction on any of the companies' use of export revenues. Therefore, the Department preliminarily finds that Agifish, Anvifish, QVD, and Binh An have established *prima facie* that they qualify for separate rates under the criteria established by *Silicon Carbide* and *Sparklers.*

Rate for Non-Selected Companies

The statute and the Department's regulations do not directly address the establishment of rates to be applied to companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. However, we normally determine the rates for non-selected companies in reviews in a manner that is consistent with section 735(c)(5) of the Act. In this review, we have only a *de minimis* company-specific dumping margin for QVD, the only mandatory respondent. However, we also have considered that we found dumping margins in previous segments of this proceeding. Therefore, based on the facts of this case, we have considered the prior rates calculated for these companies and others in choosing a reasonable method to determine the rates for these companies in the current review. *See Brake Rotors From the People's Republic of China: Final Results of 2006–2007 Administrative and New Shipper Reviews and Partial Rescission of 2006–2007 Administrative Review,* 73 FR 32678 (June 10, 2008) and accompanying Issues and Decision Memorandum at Comment 1 (''the selection of a 'reasonable method' to use when, as here, the rates of the mandatory respondents are zero and *de minimis*, must be made on a case-by-case basis and would depend on the facts of the case''). For the separate rate companies, that method is to use the most recent rate calculated for the non-selected company in question, unless we calculated in a more recent review a rate for any company that was not zero, *de minimis* or based entirely on facts available.

Anvifish recently received a calculated rate of *de minimis* in a new shipper review. *See Notice of Amended Final Results of Antidumping Duty New Shipper Review: Certain Frozen Fish Fillets from Vietnam* (''*New Shipper Review Final*''), 73 FR 47884 (August 15, 2008). Agifish has not been subject to an administrative review since the less-than-fair-value investigation in which it received a rate of 47.05 percent. *See Order.* For purposes of these preliminary results, we have assigned Anvifish's *de minimis* rate calculated in the recent new shipper review as Anvifish's non-selected separate rate in this review. For Agifish, we have assigned the rate of 15.38 percent, which represents the most recent calculated rate that is not zero or *de minimis* and not based entirely on facts available and a rate for a period that is more recent than is Agifish's rate from the investigation. For the Vietnam-wide entity (including An Xuyen), we have assigned the entity's current rate and only rate ever determined for the entity in this proceeding.

Scope of the Order

The product covered by this Order is frozen fish fillets, including regular, shank, and strip fillets and portions thereof, whether or not breaded or marinated, of the species *Pangasius Bocourti, Pangasius Hypophthalmus* (also known as *Pangasius Pangasius*), and *Pangasius Micronemus.* Frozen fish fillets are lengthwise cuts of whole fish.

[3] Binh An addressed the separate rates section of the Department's questionnaire in its November 1, 2007, submission.

The fillet products covered by the scope include boneless fillets with the belly flap intact (''regular'' fillets), boneless fillets with the belly flap removed (''shank'' fillets), boneless shank fillets cut into strips (''fillet strips/finger''), which include fillets cut into strips, chunks, blocks, skewers, or any other shape. Specifically excluded from the scope are frozen whole fish (whether or not dressed), frozen steaks, and frozen belly-flap nuggets. Frozen whole dressed fish are deheaded, skinned, and eviscerated. Steaks are bone-in, cross-section cuts of dressed fish. Nuggets are the belly-flaps. The subject merchandise will be hereinafter referred to as frozen ''basa'' and ''tra'' fillets, which are the Vietnamese common names for these species of fish. These products are classifiable under tariff article codes 1604.19.4000, 1604.19.5000, 0305.59.4000, 0304.29.6033 (Frozen Fish Fillets of the species Pangasius including basa and tra) of the Harmonized Tariff Schedule of the United States (''HTSUS'').[4] This Order covers all frozen fish fillets meeting the above specification, regardless of tariff classification. Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope of the Order is dispositive.

Non-Market Economy Country Status

In every case conducted by the Department involving Vietnam, Vietnam has been treated as a non-market economy (''NME'') country. In accordance with section 771(18)(C)(i) of the Act (''the Act''), any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See Notice of Final Results of Administrative Review: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 73 FR 15479 (March 17, 2008) and accompanying Issues and Decision Memorandum (''*3rd AR Final Results*''). None of the parties to this proceeding have contested such treatment. Accordingly, we calculated normal value (''NV'') in accordance with section 773(c) of the Act, which applies to NME countries.

[4] Until July 1, 2004, these products were classifiable under tariff article codes 0304.20.60.30 (Frozen Catfish Fillets), 0304.20.60.96 (Frozen Fish Fillets, NESOI), 0304.20.60.43 (Frozen Freshwater Fish Fillets) and 0304.20.60.57 (Frozen Sole Fillets) of the HTSUS. Until February 1, 2007, these products were classifiable under tariff article code 0304.20.60.33 (Frozen Fish Fillets of the species Pangasius including basa and tra) of the HTSUS.

Surrogate Country and Surrogate Values

On February 25, 2008, the Department sent interested parties a letter requesting comments on surrogate country selection and information pertaining to valuing factors of production (''FOP''). Binh An submitted surrogate country comments and surrogate value data on March 24, 2008. QVD and Petitioners submitted surrogate country comments and surrogate value data on May 22, 2008.

Surrogate Country

When the Department is investigating imports from an NME country, section 773(c)(1) of the Act directs it to base NV, in most circumstances, on the NME producer's FOPs, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall utilize, to the extent possible, the prices or costs of FOPs in one or more market economy countries that are: (1) At a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the ''Normal Value'' section below and in the Memorandum to the File through Alex Villanueva, Program Manager, Office 9, from Matthew Renkey, Senior Case Analyst, dated September 2, 2008.

The Department determined that Bangladesh, Pakistan, India, Indonesia, and Sri Lanka are countries comparable to Vietnam in terms of economic development.[5] Once it has identified economically comparable countries, the Department's practice is to select an appropriate surrogate country from the list based on the availability and reliability of data from the countries. *See* Department Policy Bulletin No. 04.1: Non-Market Economy Surrogate Country Selection Process (March 1, 2004). In this case, we have found that Bangladesh is a significant producer of comparable merchandise. We find Bangladesh to be a reliable source for surrogate values because Bangladesh is at a similar level of economic development pursuant to section 773(c)(4) of the Act, is a significant producer of comparable merchandise, and has publicly available and reliable data. *See* Memorandum to the File, from Alan Ray, Case Analyst, dated September 2, 2008. Thus we have selected Bangladesh as the primary surrogate country for this administrative review. However, in certain instances where Bangladeshi data was not available, we used data from Indian sources.

[5] *See* Memorandum from Carole Showers, Acting Director of Office of Policy, to Alex Villanueva, Program Manager, China/NME Group, Office 9: Antidumping Duty Administrative Review of Certain Frozen Fish Fillets from the Socialist Republic of Vietnam (Vietnam): Request for a List of Surrogate Countries (February 20, 2008).

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results in an antidumping administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results.

Affiliations

Section 771(33) of the Act provides that:

> The following persons shall be considered to be ''affiliated'' or ''affiliated persons'':
> (A) Members of a family, including brothers and sisters (whether by the whole or half blood), spouse, ancestors, and lineal descendants;
> (B) Any officer of director of an organization and such organization;
> (C) Partners;
> (D) Employer and employee;
> (E) Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting stock or shares of any organization and such organization;
> (F) Two or more persons directly or indirectly controlling, controlled by, or under common control with, any person;
> (G) Any person who controls any other person and such other person.

Additionally, section 771(33) of the Act stipulates that: ''For purposes of this paragraph, a person shall be considered to control another person if the person is legally or operationally in a position to exercise restraint or direction over the other person.''

In the final results of the third antidumping duty administrative review, the Department determined that QVD Choi Moi Farming Cooperative (''QVD Choi Moi'') would no longer be collapsed with QVD, QVD DT, and Thuan Hung pursuant to sections 771(33)(A), (B), (E), (F), and (G) of the Act and 19 CFR 351.401 (f). *See 3rd AR Final Results.* The Department also determined that QVD USA LLC (''QVD USA'') is affiliated with QVD, QVD Dong Thap, and Thuan Hung pursuant to sections 771(33)(A), (B), (E), (F), and (G) of the Act. Therefore, the Department determined to calculate a CEP through QVD USA to its first unaffiliated U.S. customer. *See 3rd AR Final Results.* The Department also determined that Beaver Street Fisheries (''BSF'') and QVD USA were not affiliated. *See 3rd AR Final Results.*

In QVD's supplemental section A response, it stated that ''{d}uring the POR there were no changes in the corporate structures of any of the QVD companies, or affiliates. There were no changes from POR 3 in the capital structure, scope of operations, affiliations, production capacity, ownership or management.'' *See* QVD's July 11, 2008, Section A Supplemental Questionnaire at 20.

For these preliminary results, based on the information on the record of this proceeding, the Department continues to find that QVD, QVD DT, and Thuan Hung should be collapsed and treated as a single entity. *See 3rd AR Final Results.* Similarly, for these preliminary results, based on the information on the record of this proceeding, the Department continues to find that QVD and QVD USA are affiliated pursuant to sections 771(33)(A), (B), (E), (F), and (G) of the Act. For these preliminary results, we also continue to find that BSF and QVD USA are not affiliated.

Fair Value Comparisons

To determine whether sales of the subject merchandise made by QVD or Binh An to the United States were at prices below NV, we compared each company's export price (''EP'') or constructed export price (''CEP''), where appropriate, to NV, as described below.

U.S. Price

For Binh An's EP sales, we used the EP methodology, pursuant to section 772(a) of the Act, because the first sale to an unaffiliated purchaser was made prior to importation and CEP was not otherwise warranted by the facts on the record. We calculated EP based on the Free-on-board foreign port price to the first unaffiliated purchaser in the United States. For the EP sale, we also deducted foreign inland freight, foreign cold storage, and international ocean freight from the starting price (or gross unit price), in accordance with section 772(c) of the Act.

In accordance with section 772(b) of the Act, we used the CEP methodology when the first sale to an unaffiliated purchaser occurred after importation of the merchandise into the United States. In this instance, we calculated CEP for all of QVD's U.S. sales through its U.S. affiliate, QVD USA, to unaffiliated customers.

For QVD's CEP sales, we made adjustments to the gross unit price for billing adjustments, rebates, foreign inland freight, international freight, foreign cold storage, U.S. marine insurance, U.S. inland freight, U.S. warehousing, U.S. inland insurance, other U.S. transportation expenses, and U.S. customs duties. In accordance with section 772(d)(1) of the Act, we also deducted those selling expenses associated with economic activities occurring in the United States, including commissions, credit expenses, advertising expenses, indirect selling expenses, inventory carry costs, and U.S. re-packing costs. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act.

Where movement expenses were provided by NME-service providers or paid for in NME currency, we valued these services using either Bangladeshi or Indian surrogate values. *See* Surrogate Value Memo. Where applicable, we used the actual reported expense for those movement expenses provided by ME suppliers and paid for in ME currency.

Bona Fide New Shipper Analysis

Consistent with the Department's practice, we investigated the *bona fide* nature of the sales made by Binh An for the new shipper review. We preliminarily find that the new shipper sales made by Binh An are *bona fide* transactions. Based on our investigation into the bona fide nature of the sales, the questionnaire responses submitted by Binh An, as well the company's eligibility for a separate rate (*see* ''Separate Rates'' section above), and the Department's preliminary determination that Binh An was not affiliated with any exporter or producer that had previously shipped subject merchandise to the United States, we preliminarily determine that Binh An has met the requirements to qualify as a new shipper during the POR. Therefore, for purposes of these preliminary results of review, we are treating Binh An's respective sales of subject merchandise to the United States as appropriate transactions for this new shipper review. We will continue to evaluate all aspects of Binh An's sales during verification and for the final results.

Duty Absorption

On October 25, 2007, Petitioner requested that the Department determine whether antidumping duties had been absorbed for U.S. sales of frozen fish fillets made during the POR by the respondents selected for review. Section 751(a)(4) of the Act provides for the Department, if requested, to determine during an administrative review initiated two or four years after publication of the order, whether antidumping duties have been absorbed by a foreign producer or exporter, if the subject merchandise is sold in the United States through an affiliated importer. In this case, only QVD sold subject merchandise in the United States through an affiliated importer. Because the antidumping duty order underlying this review was issued in 2003, and this review was initiated in 2007, we are conducting a duty absorption inquiry for this segment of the proceeding.

In determining whether the antidumping duties have been absorbed by the respondent, we presume the duties will be absorbed for those sales that have been made at less than NV. This presumption can be rebutted with evidence (*e.g.*, an agreement between the affiliated importer and unaffiliated purchaser) that the unaffiliated purchaser will pay the full duty ultimately assessed on the subject merchandise. *See, e.g., Certain Stainless Steel Butt-Weld Pipe Fittings From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Notice of Intent to Rescind in Part*, 70 FR 39735, 39737 (July 11, 2005) (unchanged in final results). On August 18, 2008, the Department requested QVD to provide evidence to demonstrate that its unaffiliated U.S. purchasers will pay any antidumping duties ultimately assessed on entries of subject merchandise.

On August 25, 2008, QVD filed a response rebutting the duty-absorption presumption by explaining that the ultimate unaffiliated U.S. purchasers paid for the duties. QVD references its financial statements and a transaction-specific analysis in which they argue that even after all price adjustments are considered, QVD has passed on duty costs to unaffiliated customers. We conclude that this information sufficiently demonstrates that the unaffiliated purchasers in the United States will ultimately pay the assessed duties. *See* QVD's August 25, 2008, Submission at 2. Therefore, we preliminarily find that antidumping duties have not been absorbed by QVD on U.S. sales made through its affiliated importer.

Normal Value

Section 773(c)(1) of the Act provides that, in the case of an NME, the Department shall determine NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. Because information on the record does not permit the calculation of NV using home-market prices, third-country prices, or constructed value and no party has argued otherwise, we calculated NV based on FOPs reported

by QVD and Binh An, pursuant to sections 773(c)(3) and (4) of the Act and 19 CFR 351.408(c).

As the basis for NV, QVD and Binh An provided FOPs used in each of the stages for processing frozen fish fillets. Our general policy, consistent with section 773(c)(1)(B) of the Act, is to value the FOPs that a respondent uses to produce the subject merchandise.

To calculate NV, we valued QVD's and Binh An's reported per-unit factor quantities using publicly available Bangladeshi, Indian, and Indonesian surrogate values. In selecting surrogate values, we considered the quality, specificity, and contemporaneity of the available values. As appropriate, we adjusted the value of material inputs to account for delivery costs. Specifically, we added surrogate freight costs to surrogate values using the reported distances from the Vietnam port to the Vietnam factory or from the domestic supplier to the factory, where appropriate. This adjustment is in accordance with the decision of the CAFC in *Sigma Corp.* v. *United States*, 117 F.3d 1401, 1407–1408 (Fed. Cir. 1997).

For those values not contemporaneous with the POR, we adjusted for inflation using data published in the International Monetary Fund's International Financial Statistics. Import data from South Korea, Thailand and Indonesia were excluded from the surrogate country import data due to generally available export subsidies. *See China Nat'l Mach. Import & Export Corp.* v. *United States*, CIT 01–1114, 293 F. Supp. 2d 1334 (CIT 2003), aff'd 104 Fed. Appx. 183 (Fed. Cir. 2004), and *Certain Cut-to-Length Carbon Steel Plate from Romania: Notice of Final Results and Final Partial Rescission of Antidumping Duty Administrative Review*, 70 FR 12651, and accompanying issues and Decision Memorandum at Comment 4 (March 15, 2005). Additionally, we excluded prices from NME countries and imports that were labeled as originating from an ''unspecified'' Asian country. The Department excluded these imports because it could not ascertain whether they were from either an NME country or a country with general export subsidies. We converted the surrogate values to U.S. dollars as appropriate, using the official exchange rate recorded on the dates of sale of subject merchandise in this case, obtained from *http://www.ia.ita.doc.gov/exchange/index.html.* For further detail, see Surrogate Values Memo.

Preliminary Results of the Review

As a result of our review, we preliminarily find that the following margins exist for the period August 1, 2006, through July 31, 2007:

CERTAIN FROZEN FISH FILLETS FROM VIETNAM

Manufacturer/exporter	Weighted-average margin
QVD [6]	*de minimis*
Anvifish	*de minimis*
Agifish	15.38
Binh An	*de minimis*
Vietnam-wide Entity [7]	63.88

[6] This rate is applicable to the QVD Single Entity which includes QVD, QVD DT, and Thuan Hung.
[7] Includes An Xuyen.

Public Comment

The Department will disclose to parties of this proceeding the calculations performed in reaching the preliminary results within ten days of the date of announcement of the preliminary results. An interested party may request a hearing within 30 days of publication of the preliminary results. *See* 19 CFR 351.310(c). Interested parties may submit written comments (case briefs) within 20 days of publication of the preliminary results and rebuttal comments (rebuttal briefs), which must be limited to issues raised in the case briefs, within five days after the time limit for filing case briefs. *See* 19 CFR 351.309(c)(1)(ii) and 19 CFR 351.309(d). Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Further, the Department requests that parties submitting written comments provide the Department with a diskette containing the public version of those comments. Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days of publication of the preliminary results. The assessment of antidumping duties on entries of merchandise covered by this review and future deposits of estimated duties shall be based on the final results of this review.

Assessment Rates

Upon completion of this administrative review, pursuant to 19 CFR 351.212(b), the Department will calculate an assessment rate on all appropriate entries. For the mandatory respondent, QVD, and new shipper, Binh An, we will calculate importer-specific duty assessment rates on a per-unit basis.[8] Where the assessment rate is *de minimis*, we will instruct CBP to assess duties on all entries of subject merchandise by that importer. We will instruct CBP to liquidate entries containing merchandise from the PRC-wide entity at the PRC-wide rate we determine in the final results of review. We will issue assessment instructions to CBP 15 days after the date of publication of the final results of review.

Cash-Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis*, the cash deposit will be zero); (2) for previously investigated or reviewed Vietnam and non-Vietnam exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all Vietnam exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the Vietnam-wide rate of 63.88 percent, and (4) for all non-Vietnam exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Vietnam exporters that supplied that non-Vietnam exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR.

[8] We divided the total dumping margins (calculated as the difference between NV and EP or CEP) for each importer by the total quantity of subject merchandise sold to that importer during the POR to calculate a per-unit assessment amount. We will direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.*, per-kilogram) rates by the weight in kilograms of each entry of the subject merchandise during the POR.

Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this determination in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 2, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–20755 Filed 9–5–08; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

A–570–506

Porcelain–on-Steel Cooking Ware from the People's Republic of China: Notice of Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on porcelain–on-steel cooking ware from the People's Republic of China (''PRC'') covering the period December 1, 2006, to November 30, 2007. The Department has preliminarily determined to apply adverse facts available to the PRC–wide entity, which includes Xiamen Songson Plastic Hardware Co., Ltd. (''Songson''), the only respondent in this review. If these preliminary results are adopted in the final results of this review, the Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on entries of subject merchandise during the period of review (''POR''). Interested parties are invited to comment on these preliminary results. *See* the ''Preliminary Results of Review'' section of this notice.

EFFECTIVE DATE: September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Toni Dach or Scot Fullerton, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1655 or (202) 482–1386, respectively.

SUPPLEMENTARY INFORMATION:

Background

In response to a request from Columbian Home Products, LLC (''petitioner'') and OXO International Ltd., an importer of the subject merchandise, the Department of Commerce (the ''Department'') initiated an administrative review of Songson's exports of merchandise covered by the antidumping duty order on porcelain–on-steel cooking ware from the PRC. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 73 FR 4829 (January 28, 2008) (''Initiation Notice'').

On January 31, 2008, the Department issued its sections A, C and D antidumping duty questionnaire to Songson. The section A response was due on February 21, 2008, and the sections C and D response, as well as U.S. sales and factors of production (''FOP'') reconciliations, were due on March 10, 2008. On February 19, 2008, Songson requested an extension, until March 6, 2008, to file its section A response, and until March 24, 2008, to submit its sections C and D responses. On February 20, 2008, the Department granted Songson's extension request. We received the company's response to section A via regular mail on March 6, 2008. On March 14, 2008, the Department rejected Songson's section A response, as it was not filed in accordance with the Department's regulations. *See* Letter from the Department of Commerce to Xiamen Songson Plastic Hardware Co., Ltd., Re: Rejection of Section A Questionnaire Response (March 14, 2008). We granted Songson a second opportunity to file a complete section A response, and Songson submitted its revised section A response on March 28, 2008 (''Songson section A response''). Songson did not submit its sections C and D responses, or the required sales and FOP reconciliations by the extended due date, or on any date thereafter.

Period of Review

The POR is December 1, 2006, through November 30, 2007.

Scope of Order

The merchandise covered by this order is porcelain–on-steel cooking ware from the PRC, including tea kettles, which do not have self–contained electric heating elements. All of the foregoing are constructed of steel and are enameled or glazed with vitreous glasses. The merchandise is currently classifiable under the United States Harmonized Tariff Schedule (''USHTS'') item 7323.94.00. USHTS item numbers are provided for convenience and customs purposes. The written description of the scope remains dispositive.

Non–Market-Economy Country

The Department considers the PRC to be a non–market economy (''NME'') country. *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Coated Free Sheet Paper from the People's Republic of China*, 72 FR 30758, 30760 (June 4, 2007), unchanged in *Final Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from the People's Republic of China*, 72 FR 60632 (October 25, 2007). In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. No party has challenged the designation of the PRC as an NME country in this investigation. Therefore, we continue to treat the PRC as an NME country for purposes of this preliminary determination.

Separate Rates

A designation of a country as an NME remains in effect until it is revoked by the Department. *See* section 771(18)(C)(i) of the Act. Accordingly, there is a rebuttable presumption that all companies within the PRC are subject to government control and, thus, should be assessed a single antidumping duty rate. It is the Department's standard policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports.

To establish whether a company operating in a non–market economy country (''NME'') is sufficiently independent from government control to be entitled to a separate rate, the Department analyzes each exporting entity under the test established in the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588 (May 6, 1991), as amplified by the Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China, 59 FR 22585 (May 2, 1994). Under the separate rates criteria, the Department assigns separate rates in NME cases only if the respondent can demonstrate the absence of both *de jure* and *de facto* governmental control over export activities.

De Jure Control

Evidence supporting, though not requiring, a finding of absence of *de jure* government control over export activities includes: (1) an absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies.

As evidence of the absence of *de jure* government control over Songson's export activities, the Department requested that Songson provide any legislative enactments or other formal measures by the government that centralize or decentralize control of its export activities. In response, Songson responded ''N/A'' and did not provide the required laws applicable to Songson's export activities. *See* Songson section A response at 8. In addition, the Department requested that Songson describe the licensing process, provide the dates of any license applications, as well as all copies of paperwork and proposals submitted to government authorities regarding the license. Although Songson provided the Department with a copy of its approved business license, it did not provide any of the additional requested information noted above. *See Id.* Therefore, based on the record evidence, the Department cannot determine that there is an absence of *de jure* control over the export activities of Songson.

De Facto Control

A determination of absence of *de facto* government control over exports is based on the following four factors: (1) whether the exporter sets its own export prices independently of the government and without the approval of a government authority; (2) whether the exporter retains the proceeds from its sales and makes independent decisions regarding the disposition of profits or financing of losses; (3) whether the exporter has the authority to negotiate and sign contracts and other agreements; and (4) whether the exporter has autonomy from the government regarding the selection of management. *See e.g. Final Determination of Sales at Less than Fair Value: Certain Cut–to-Length Carbon Steel Plate from Ukraine*, 62 FR 61754, 61758 (November 19, 1997).

Songson asserted that it: (1) it establishes its own export prices; (2) negotiates contracts without guidance from any governmental entities or organizations; (3) makes its own personnel decisions; and (4) retains the proceeds of its export sales, uses profits according to its business needs, and has the authority to sell its assets and to obtain loans. *See* Songson section A response. However, Songson did not provide the Department with adequate information or documentation to support these claims in order to demonstrate that the company is not under the *de facto* control of the PRC government with respect to its export activities. For example, although the Department requested in its section A questionnaire that Songson provide evidence of price negotiations for its POR sales, Songson did not provide this requested documentation, and provided no explanation as to why it did not do so. *See Id.* at 9–10. In addition, although the Department requested that Songson describe how it negotiates sales to the United States, it provided no such description of its sales negotiations. *See Id.* at 14. The Department also requested that Songson describe how its management is selected. Although Songson stated that its general manager was appointed ''by the board meeting,'' it provided no description of who selects its other managers, and provided no description of how the board selects the general manager. *See Id.* at 10. In addition, Songson has asserted that it established its own export prices. However, in response to the Department's request for a description of the process by which Songson sets prices with its U.S. customers, Songson replied ''N/A.'' *See Id.* at 9–10.

Because we have been unable to fully analyze the level of *de facto* control over Songson's export activities due to the numerous deficiencies in Songson's Section A response, the Department concludes that the company has not satisfactorily demonstrated the absence of *de facto* control by the PRC government. Therefore, the Department has determined that Songson has not demonstrated that it qualifies for a separate rate. Because Songson did not demonstrate its eligibility for a separate rate, we have preliminarily determined that it is part of the PRC–wide entity. In the initiation notice, the Department stated that if one of the companies that we initiated a review on does not qualify for a separate rate, all other exporters of porcelain–on-steel cooking ware from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC–wide entity, of which the named exporter is a part. *See Initiation Notice* at footnote 6. As a result, we determine that it is necessary to review the PRC–wide entity, including Songson, in this segment of the proceeding.

Application of Adverse Facts Available

As discussed below, we find that it is appropriate to apply facts otherwise available on the record to the PRC–wide entity pursuant to section 776(a) of the Act. Section 776(a)(2) of the Act provides that, if an interested party: (A) withholds information that has been requested by the Department; (B) fails to provide such information in a timely manner or in the form or manner requested subject to sections 782(c)(1) and (e) of the Act; (C) significantly impedes a proceeding under the antidumping statute; or (D) provides such information, but the information cannot be verified, the Department shall, subject to section 782(d) of the Act, use facts otherwise available in reaching the determination. In the instant case, Songson, which is part of the PRC–wide entity, has withheld information by not providing (1) capital verification reports, *see* Songson section A response at 3.f.; (2) a description of the process by which it sets prices with its U.S. customers, *see* Songson section A response at 4.h.; (3) a description, and copies of, its agreements for sales to the U.S., *see* Songson section A response at 4.c.; (4) a description of the companies accounting and financial reporting practices, *see* Songson section A response at 5.a.; (5) a chart of accounts, see Songson section A response at 5.b.; (6) a description of the licensing process, or copies of paperwork and proposals submitted to the government in order to obtain a business license, *see* Songson section A response at 2.e.(iv); and (7) sales or FOP reconciliations as requested at Appendix V of the Department's questionnaire. The Department requires this information to evaluate U.S. sales and FOP reconciliations, as well as the nature and extent of a respondent's affiliations, which may impact the way export sales are treated in the calculation of a dumping margin. In addition, Songson did not provide a section C and D questionnaire response, which the Department requires to calculate a dumping margin. As the Department was not provided with this information, we have no information with which to calculate an antidumping duty margin. Therefore, the Department finds that facts available pursuant to sections 776(a)(2)(A) and (C) of the Act is warranted for the PRC–wide entity, including Songson, as Songson has withheld the information noted above that was requested by the Department, and has significantly impeded the proceeding by not providing

information necessary to complete this administrative review.

Section 776(b) of the Act provides that if the Department determines that a party has failed to cooperate to the best of its ability, in selecting from among the facts available, the Department may use an inference that is adverse to the interests of that party. As noted above, Songson did not provide the Department with a complete section A response or a sections C and D questionnaire response. Therefore, by failing to provide the necessary information within its possession, the PRC–wide entity, including Songson, has failed to cooperate to the best of its ability, and we find it appropriate pursuant to sections 776(a)(2) and 776(b) of the Act, to apply total AFA to the PRC–wide entity for these preliminary results.

Selection of AFA Rate

In deciding which facts to use as AFA, section 776(b) of the Act and 19 CFR 351.308(c)(1) authorize the Department to rely on information derived from: (1) the petition; (2) a final determination in the investigation; (3) any previous review or determination; or (4) any information placed on the record. In reviews, it is the Department's practice to select, as AFA, the highest rate determined for any respondent in any segment of the proceeding. *See, e.g., Freshwater Crawfish Tail Meat from the People's Republic of China; Notice of Final Results of Antidumping Duty Administrative Review*, 68 FR 19504, 19506 (April 21, 2003).

The Court of International Trade (''CIT'') and the Federal Circuit have consistently upheld the Department's practice. *See Rhone Poulenc, Inc. v. United States*, 899 F.2d 1185, 1190 (Fed. Cir. 1990) (''*Rhone Poulenc*''); *NSK Ltd. v. United States*, 346 F. Supp. 2d 1312, 1335 (Ct. Int'l Trade 2004) (upholding a 73.55% total AFA rate, the highest available dumping margin from a different respondent in a less than fair value investigation); *see also Kompass Food Trading Int'l v. United States*, 24 CIT 678, 689 (2000) (upholding a 51.16% total AFA rate, the highest available dumping margin from a different, fully cooperative respondent); and *Shanghai Taoen International Trading Co., Ltd. v. United States*, 360 F. Supp. 2d 1339 (CIT February 17, 2005) (upholding a 223.01 percent total AFA rate, the highest available dumping margin from a different respondent in a previous administrative review).

The Department's practice when selecting an adverse rate from among the possible sources of information is to ensure that the margin is sufficiently adverse ''as to effectuate the purpose of the facts available role to induce respondents to provide the Department with complete and accurate information in a timely manner.'' *See Static Random Access Memory Semiconductors from Taiwan; Final Determination of Sales at Less than Fair Value*, 63 FR 8909, 8932 (February 23, 1998). The Department's practice also ensures Athat the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.@ See Statement of Administrative Action (''SAA'') accompanying the URAA, H.R. Rep. No. 103–316 at 870 (1994). *See also Final Determination of Sales at Less than Fair Value: Certain Frozen and Canned Warmwater Shrimp from Brazil*, 69 FR 76910 (December 23, 2004); *see also D&L Supply Co. v. United States*, 113 F.3d 1220, 1223 (Fed. Cir. 1997). In choosing the appropriate balance between providing respondents with an incentive to respond accurately and imposing a rate that is reasonably related to the respondent's prior commercial activity, selecting the highest prior margin reflects a common sense inference that the highest prior margin is the most probative evidence of current margins, because, if it were not so, the respondent, knowing of the rule, would have produced current information showing the margin to be less. *Rhone Poulenc*, 899 F.2d at 1190.

Consistent with section 776(b)(3) of the Act, court precedent, and its practice, the Department has assigned the rate of 66.65 percent, calculated in the less–than-fair–value investigation,[1] the highest rate assigned in any segment of the proceeding, to the PRC–wide entity, including Songson, as AFA. *See, e.g., Brake Rotors from the People=s Republic of China: Rescission of Second New Shipper Review and Final Results and Partial Rescission of First Antidumping Duty Administrative Review*, 64 FR 61581, 61584 (November 12, 1999). As discussed further below, this rate has been corroborated.

Corroboration of Secondary Information Used as AFA

Section 776(c) of the Act provides that when the Department selects from among the facts otherwise available and relies on ''secondary information,'' the Department shall, to the extent practicable, corroborate that information from independent sources reasonably at the Department's disposal. The SAA states that ''corroborate'' means to determine that the information used has probative value. *See SAA* at 870. The Department has determined that to have probative value, information must be reliable and relevant. *See Certain Tissue Paper Products from the People's Republic of China: Final Results and Final Rescission, In Part, of Antidumping Duty Administrative Review*, 72 FR 58642 (October 16, 2007) and accompanying Issues and Decision Memorandum at Comment 6. The SAA also states that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation. *See SAA* at 870; *see also Final Determination of Sales at Less Than Fair Value: Live Swine from Canada*, 70 FR 12181, 12184 (March 11, 2005).

To be considered corroborated, information must be found to be both reliable and relevant. Unlike other types of information, such as input costs or selling expenses, there are no independent sources for calculated dumping margins. The only sources for calculated margins are administrative determinations. The AFA rate we are applying in the current review was calculated during the Less Than Fair Value Investigation. *See Porcelain–on-Steel Cooking Ware from the People's Republic of China; Final Determination of Sales at Less Than Fair Value*, 51 FR 36419 (October 10, 1986) (''*LTFV Investigation*''). The Department corroborated the information used to calculate the 66.65 percent rate in the *LTFV investigation*, finding the rate to be both reliable and relevant. Furthermore, the AFA rate we are applying for the current review was applied in reviews subsequent to the LTFV Investigation and the Department received no information that warranted revisiting the issue. *See, e.g., Porcelain–on-Steel Cooking Ware from the People's Republic of China: Notice of Final Results of Antidumping Duty Administrative Review*, 71 FR 24641 (April 26, 2006). No information has been presented in the current review that calls into question the reliability of this information. Thus, the Department finds that the information is reliable.

With respect to the relevance aspect of corroboration, the Department will consider information reasonably at its disposal to determine whether a margin continues to have relevance. Where circumstances indicate that the selected margin is not appropriate as AFA, the Department will disregard the margin and determine an appropriate margin. *See Fresh Cut Flowers from Mexico:*

[1] *See Porcelain-on-Steel Cooking Ware from the People's Republic of China; Final Determination of Sales at Less Than Fair Value*, 51 FR 36419 (October 10, 1986).

Final Results of Antidumping Duty Administrative Review, 61 FR 6812 (February 22, 1996), (where the Department disregarded the highest margin in that case as adverse best information available (the predecessor to facts available) because the margin was based on another company's uncharacteristic business expense, resulting in an unusually high margin). Similarly, the Department does not apply a margin that has been discredited. *See D & L Supply Co. v. United States*, 113 F.3d 1220, 1221 (Fed. Cir. 1997) (the Department will not use a margin that has been judicially invalidated). There is no information reasonably available at our disposal in this review to corroborate the relevance of the AFA rate in question, which, as discussed above, was last corroborated in the *LTFV Investigation*. We cannot use the margin calculations of other companies because there are no other respondents in this review. Therefore, because there is no record evidence calling into question the relevance of the selected AFA rate, we find that it is relevant for use in this administrative review.

Because the AFA rate, 66.65 percent, is both reliable and relevant, we determine that it has probative value. As a result, the Department determines that the 66.65 percent rate is corroborated for the purposes of this administrative review and may reasonably be applied to the PRC–wide entity, as AFA.

Preliminary Results of the Review

The Department preliminarily finds that the following margins exist for the following exporters under review during the period December 1, 2006, through November 30, 2007:

PORCELAIN–ON-STEEL COOKING WARE FROM THE PRC

Manufacturer/Exporter	Weighted–Average Margin (Percent)
PRC–Wide Entity (which includes Xiamen Songson Plastic Hardware Co., Ltd.)	66.65

Any interested party may request a hearing within 30 days of publication of this notice. Interested parties who wish to request a hearing or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration within 30 days of the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c).

Issues raised in the hearing will be limited to those raised in case and rebuttal briefs. Case briefs from interested parties may be submitted not later than 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days later, pursuant to 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument. Parties are also encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any such written briefs or at the hearing, if held, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment of Antidumping Duties

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of the final results of this review. If these preliminary results are adopted in our final results of the review, we will direct CBP to assess the resulting rate against the entered customs value for the subject merchandise on each importer's/customer's entries during the POR, as appropriate.

Cash Deposit Requirements

The following cash–deposit requirements will be effective upon publication of the final results for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) for subject merchandise exported by the PRC, including Songson, the cash–deposit rate will be equal to 66.65 percent; (2) the cash–deposit rate for PRC exporters who received a separate rate in a prior segment of the proceeding will continue to be the rate assigned in that segment of the proceeding; (3) for all other PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash–deposit rate will be the PRC–wide rate of 66.65 percent; (4) for all non–PRC exporters of subject merchandise, the cash–deposit rate will be the rate applicable to the PRC exporter that supplied that exporter.

These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice is in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: September 2, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–20748 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On August 29, 2008, Nacional de Acero S.A. de C.V. (''Nacional'') filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the Final Injury Determination made by the United States International Trade Commission respecting Light-Walled Rectangular Pipe and Tube from China, Korea, and Mexico. The determination was published in the **Federal Register** (73 FR 45244) on August 4, 2008. The NAFTA Secretariat has assigned Case Number USA–MEX–2008–1904–04 to this request.

FOR FURTHER INFORMATION CONTACT: Valerie Dees, United States Secretary, NAFTA Secretariat, Suite 2061, 14th

and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada, and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement on August 29, 2008, requesting panel review of the determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is September 29, 2008);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is October 14, 2008); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: September 3, 2008.

Valerie Dees,

United States Secretary, NAFTA Secretariat.

[FR Doc. E8–20738 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice and Call for Applications for the International Buyer Program for the Period January 1, 2010 through December 31, 2010

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice and Call for Applications for the International Buyer Program for the period January 1, 2010 through December 31, 2010.

SUMMARY: This notice sets forth objectives, procedures and application review criteria associated with support for domestic trade shows by the International Buyer Program (IBP) of the U.S. Department of Commerce (DOC). This announcement covers selection for International Buyer Program participation for calendar year 2010 (January 1, 2010 through December 31, 2010).

The International Buyer Program was established to bring international buyers together with U.S. firms by promoting leading U.S. trade shows in industries with high export potential. The International Buyer Program emphasizes cooperation between the DOC and trade show organizers to benefit U.S. firms exhibiting at selected events and provides practical, hands-on assistance such as export counseling and market analysis to U.S. companies interested in exporting. The assistance provided to show organizers includes worldwide overseas promotion of selected shows to potential international buyers, end-users, representatives and distributors. The worldwide promotion is executed through the offices of the DOC U.S. and Foreign Commercial Service (hereinafter referred to as the Commercial Service) in more than 70 countries representing the United States' major trading partners, and also in U.S. Embassies in countries where the Commercial Service does not maintain offices. The DOC expects to select approximately 40 trade shows for the January 1, 2010 through December 31, 2010 period from among applicants to the program. Shows selected for the International Buyer Program will provide a venue for U.S. companies interested in expanding their sales into international markets. Successful show organizer applicants will be required to enter into a Memorandum of Agreement (MOA) with the DOC. The MOA constitutes an agreement between the DOC and the show organizer specifying which responsibilities are to be undertaken by the DOC as part of the International Buyer Program and, in turn, which responsibilities are to be undertaken by the show organizer. Anyone requesting application information will be sent a sample copy of the MOA along with the application and a copy of this **Federal Register** Notice. The responsibilities to be undertaken by the DOC will be carried out by the Commercial Service.

DATES: Applications must be received within 60 days after the publication date of this **Federal Register** Notice.

ADDRESSES: International Buyer Program, Global Trade Programs, U.S. and Foreign Commercial Service, International Trade Administration, U.S. Department of Commerce, 1300 Pennsylvania Ave., Ronald Reagan Center, Suite 800M—Mezzanine Level—Atrium North, Washington, DC 20004. Telephone (202) 482–4207; Facsimile: (202) 482–7800; E-mail: *Blanche.Ziv@mail.doc.gov* (for deadline purposes, facsimile and e-mail applications will be accepted as interim applications, to be followed by signed original applications to be received within five (5) business days after the application deadline). To ensure that applications are timely received by the deadline, applicants are strongly urged to send applications by hand delivery service.

FOR FURTHER INFORMATION CONTACT: Blanche Ziv, Manager, International Buyer Program, Global Trade Programs, U.S. and Foreign Commercial Service, International Trade Administration, U.S. Department of Commerce, 1300 Pennsylvania Ave., Ronald Reagan Center, Suite 800M—Mezzanine Level—Atrium North, Washington, DC 20004; Telephone (202) 482–4207; Facsimile: (202) 482–7800; E-mail: *Blanche.Ziv@mail.doc.gov.*

SUPPLEMENTARY INFORMATION: The Commercial Service is accepting applications for the International Buyer Program for trade events taking place between January 1, 2010, and December 31, 2010. A participation fee of $8,000 for shows of five days or less is required. For trade shows more than five days in duration, or requiring more than one International Business Center, a participation fee of $14,000 is required. For trade shows ten days or more in duration, and/or requiring more than two International Business Centers, the participation fee will be negotiated, but shall not be less than $19,500.

Under the International Buyer Program, the Commercial Service seeks to bring together international buyers with U.S. firms by selecting and promoting in international markets U.S.

domestic trade shows covering industries with high export potential. Selection of a trade show is valid for one event, i.e., a trade show organizer seeking selection for a recurring event must submit a new application for selection for each occurrence of the event. Even if the event occurs more than once in the 12-month period covered by this announcement, the trade show organizer must submit a separate application for each event.

The Commercial Service expects to select approximately 40 events from among applicants to the program for the January 1, 2010 and December 31, 2010 period. The Commercial Service will select those events that are determined to most clearly meet the Commercial Service's statutory mandate to promote U.S. exports, especially those of small- and medium-sized enterprises, and that best meet the selection criteria articulated below.

The DOC selects trade shows to be International Buyer Program partners that it determines to be leading international trade shows appropriate for participation by U.S. exporting firms and for promotion in overseas markets by U.S. Embassies and Consulates. Selection as an International Buyer Program partner does not constitute a guarantee by the U.S. Government of the show's success. International Buyer Program partnership status is not an endorsement of the show organizer except as to its international buyer activities. Non-selection should not be viewed as a finding that the event will not be successful in the promotion of U.S. exports.

Exclusions: Trade shows that are either first-time or horizontal (non-industry specific) events will not be considered.

General Selection Criteria: The Commercial Service will select shows to be International Buyer Program partners that, in the judgment of the Commercial Service, best meet the following criteria:

(a) *Intellectual Property Rights Protection:* The trade show organizer includes in the terms and conditions of its exhibitor contracts provisions for the protection of intellectual property rights (IPR); has procedures in place at the trade show to address IPR infringement, which, at a minimum, provides information to help U.S. exhibitors procure legal representation during the trade show; and agrees to assist the DOC to reach and educate U.S. exhibitors on the Strategy Targeting Organized Piracy (STOP!), IPR protection measures available during the show, and the means to protect IPR in overseas markets, as well as in the United States.

(b) *Export Potential:* The trade show promotes products and services from U.S. industries that have high export potential, as determined by DOC sources, e.g., Commercial Service best prospects lists and U.S. export statistics (certain industries are rated as priorities by our domestic and international commercial officers in their Country Commercial Guides, available through the Web site, *http://www.export.gov*).

(c) *International Interest:* The trade show meets the needs of a significant number of overseas markets and corresponds to marketing opportunities as identified by the posts in their Country Commercial Guides (e.g., best prospect lists). Previous international attendance at the show may be used as an indicator.

(d) *Scope of the Show:* The event must offer a broad spectrum of U.S. made products and services for the subject industry. Trade shows with a majority of U.S. firms as exhibitors are given priority.

(e) *U.S. Content of Show Exhibitors:* Trade shows with exhibitors featuring a high percentage of U.S. products or products with a high degree of U.S. content will be preferred. Generally, to have ''U.S. content,'' products and services to be exhibited should be: (i) Produced or manufactured in the United States; or, (ii) if produced or manufactured outside of the United States, be marketed under the name of a U.S. firm and have U.S. content representing at least 51 percent of the value of the finished product or service being exported. U.S.-sourced inputs that may be considered as contributing to U.S. content, to the extent that they are incorporated into the finished product or service being exported, may include but are not limited to: Materials; components; packaging; labor; production equipment and factory overhead; research and development; design; intellectual property; warehousing; distribution; sales; administration and management; advertising; and marketing and promotion.

(f) *Stature of the Show:* The trade show is clearly recognized by the industry it covers as a leading event for the promotion of that industry's products and services both domestically and internationally, and as a showplace for the latest technology or services in that industry.

(g) *Exhibitor Interest:* There is demonstrated interest on the part of U.S. exhibitors in receiving international business visitors during the trade show. A significant number of U.S. exhibitors should be new-to-export (NTE) or seeking to expand their sales into additional export markets.

(h) *Overseas Marketing:* There has been a demonstrated effort to market prior shows overseas. In addition, the applicant should describe in detail the international marketing program to be conducted for the event, and explain how efforts should increase individual and group international attendance. (Planned cooperation with Visit USA Committees overseas is desirable. For more information on Visit USA Committees go to: *http://www.tia.org/International/VUSA.html*.)

(i) *Logistics:* The trade show site, facilities, transportation services, and availability of accommodations at the site of the exhibition must be capable of accommodating large numbers of attendees whose native language will not be English.

(j) *Cooperation:* The applicant demonstrates a willingness to cooperate with the Commercial Service to fulfill the program's goals and adhere to the target dates set out in the MOA and in the event timetables, both of which are available from the program office (see the **''FOR FURTHER INFORMATION''** section above). Past experience in the International Buyer Program will be taken into account in evaluating the applications received for the January 1, 2010, through December 31, 2010, period.

(k) *Delegation Incentives:* Show organizers should list or identify a range of incentives to be offered to delegations and/or delegation leaders recruited by the Commercial Service overseas posts. Examples of incentives to international visitors and to organized delegations include, but are not limited to: Waived or reduced admission fees; special organized events, such as receptions, meetings with association executives, briefings, and site tours; and complimentary accommodations for delegation leaders. Waived or reduced admission fees are required for international attendees who are members of Commercial Service recruited delegations under this program. Delegation leaders also must be provided complimentary admission to the event.

Legal Authority: The Commercial Service has the legal authority to enter into MOAs with show organizers (partners) under the provisions of the Mutual Educational and Cultural Exchange Act of 1961 (MECEA), as amended (22 U.S.C. sections 2455(f) and 2458(c)). MECEA allows the Commercial Service to accept contributions of funds and services from firms for the purposes of furthering its mission. The statutory program

authority for the Commercial Service to conduct the International Buyer Program is 15 U.S.C. 4724.

The Office of Management and Budget (OMB) has approved the information collection requirements of the application to this program under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (OMB Control No. 0625–0151). Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

Dated: September 2, 2008.

Blanche Ziv,

Manager, International Buyer Program, U.S. and Foreign Commercial Service, International Trade Administration, U.S. Department of Commerce.

[FR Doc. E8–20756 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XK26

Marine Mammals; File No. 13430

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the NMFS National Marine Mammal Laboratory, (Responsible Party: Dr. John Bengtson, Director), Seattle, WA, has applied for a permit to conduct research on marine mammals.

DATES: Written, telefaxed, or e-mail comments must be received on or before October 8, 2008.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206)526–6150; fax (206)526–6426.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301)427–2521, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing e-mail comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 13430.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Kate Swails, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to conduct research on Pacific harbor seals (*Phoca vitulina*), California sea lions (*Zalophus californianus*), and northern elephant seals (*Mirounga angustirostris*) within coastal waters and on pinniped rookeries and haul outs of Washington and Oregon. Research activities would include aerial, vessel, and ground surveys; capture for collection of tissue samples, attachment of scientific instruments and application of marks (flipper tags, brands, etc.); and underwater playback experiments. The purpose of the research is to investigate: (1) abundance and distribution of harbor seals; (2) food habits and foraging ecology of harbor seals; (3) the ecology of contaminants, environmental toxins and infectious pathogens in harbor seals; (4) harbor seal life history parameters; (5) population substructure in harbor seals in Washington and Oregon; (6) abundance, distribution and health of California sea lions in Washington and Oregon; (7) California sea lion food habits and predation of threatened, endangered, and/or depleted fish stocks in Washington and Oregon; and (8) the abundance, distribution and health of northern elephant seals. The objective of the research is to provide information necessary for stock assessments and for management, including management of marine mammal predation on threatened and endangered salmon. The permit would be valid for five years and would authorize level B and level A harassment, including research-related mortality of limited numbers of each species. Please refer to the table in the application for the numbers of animals proposed for taking, and the locations and manner of such taking.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a draft environmental assessment (EA) has been prepared to examine whether significant environmental impacts could result from issuance of the proposed scientific research permit. Based on the analyses in the EA, it is NMFS initial determination that issuance of the permit would not significantly impact the quality of the human environment and that preparation of an environmental impact statement is not required.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 2, 2008.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–20773 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XK28

Mid-Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Council's (MAFMC) Dogfish Monitoring Committee will hold a public meeting.

DATES: The meeting will be held on Thursday, September 25, 2008, from 10 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Sheraton Providence Airport Hotel, 1850 Post Road, Warwick, RI 02886; telephone: (401) 738–4000.

Council address: Mid-Atlantic Fishery Management Council, 300 S. New Street, Room 2115, Dover, DE 19904; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council, 300 S. New Street, Room 2115, Dover, DE 19904; telephone: (302) 674–2331, extension 19.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to review the Atlantic States Marine Fishery Commission Technical Committee's recommendations for annual catch limits and accountability measures regarding specifying quotas and management measures for the upcoming 2009 fishing year for spiny dogfish. Management measures that will be discussed may include, but not necessarily be limited to, quotas and daily landings limits.

Multiple-year management measures for fishing years 2010 and 2011 may also be addressed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the MAFMC's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Bryan at the Mid-Atlantic Council Office, (302) 674–2331 extension 18, at least 5 days prior to the meeting date.

Dated: September 3, 2008.

Tracey L. Thompson,

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

[FR Doc. E8–20679 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office (USPTO).

Title: Representative and Address Provisions.

Form Number(s): PTO/SB/80/81/83/84/122/123/124/125 and PTO–2248.

Agency Approval Number: 0651–0035.

Type of Request: Revision of a currently approved collection.

Burden: 33,357 hours annually.

Number of Respondents: 568,902 responses per year.

Avg. Hours per Response: The USPTO estimates that it will take the public approximately 3 minutes (0.05 hours) to 1.5 hours to submit the information in this collection, including the time to gather the necessary information, prepare the appropriate form or document, and submit the completed request.

Needs and Uses: Under 35 U.S.C. 2 and 37 CFR 1.31–1.36, this information collection is used by the public to grant or revoke power of attorney in a patent application, to withdraw as attorney or agent of record, to authorize a practitioner to act in a representative capacity, to change the correspondence address for one or more applications or patents, to request a Customer Number, to designate or change the correspondence address or list of practitioners associated with a Customer Number, and to associate a patent application with a Customer Number. The USPTO's Customer Number practice permits authorized individuals to change the correspondence address or representatives of record for a number of applications or patents with one change request instead of filing separate requests for each application or patent. The USPTO uses the information in this collection to determine who is authorized to take action in an application or patent on behalf of the applicant or assignee and where to send correspondence regarding an application or patent.

The USPTO is revising the Power of Attorney and Correspondence Address Indication Form (PTO/SB/81) to include revocations of power of attorney and to eliminate the need for the separate form Revocation of Power of Attorney With New Power of Attorney and Change of Correspondence Address (PTO/SB/82). Consequently, Form PTO/SB/81 will be renamed ''Power of Attorney or Revocation of Power of Attorney With a New Power of Attorney and Change of Correspondence Address'' and Form PTO/SB/82 will be deleted from this collection. The USPTO is revising another form in this collection, Request for Withdrawal as Attorney or Agent and Change of Correspondence Address (PTO/SB/83), to allow the practitioner requesting withdrawal to certify that proper notice has been given to the client and that all papers and property to which the client is entitled have been delivered.

The USPTO is deleting two additional items from this collection. The electronic power of attorney forms that were previously included in this collection are being deleted due to the retirement of the USPTO's previous electronic filing system (EFS) software in favor of a new Web-based online submission system (EFS-Web). The Customer Number Upload Spreadsheet for PCT Applications is being deleted from this collection because it is no longer in use. Applicants seeking to associate an established PCT application with an existing Customer Number may submit a Request to Update a PCT Application With a Customer Number (PTO–2248).

Affected Public: Individuals or households, businesses or other for-profits, and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by any of the following methods:

- *E-mail: Susan.Fawcett@uspto.gov.* Include ''0651–0035 copy request'' in the subject line of the message.
- *Fax:* 571–273–0112, marked to the attention of Susan Fawcett.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before October 8, 2008 to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

Dated: August 29, 2008.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E8–20695 Filed 9–5–08; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Provisional Patent Application Concerning Ratchet Hook Tourniquet

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6 and 404.7, announcement is made of the availability for licensing of the invention set forth in U.S. Provisional Patent Application Serial No. 61/090,042 entitled ''Ratchet Hook Tourniquet,'' filed August 19, 2008. The United States Government, as represented by the Secretary of the Army, has rights in this invention.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR-JA, 504 Scott Street, Fort Detrick, Frederick, MD 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664, both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: The invention is an improvement of the traditional ratchet tourniquet used to stop uncontrollable bleeding from gunshot wounds and blast injuries to the arms and legs.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–20724 Filed 9–5–08; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Availability of Final Supplemental Environmental Impact Statement for Atlantic Coast of Maryland Shoreline Protection Project—General Reevaluation Study: Borrow Sources for 2010–2044, Ocean City, MD

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of availability.

SUMMARY: In accordance with the requirements of the National Environmental Policy Act (NEPA), the Baltimore District, U.S. Army Corps of Engineers (USACE), has prepared a Final Supplemental Environmental Impact Statement (SEIS) for the Atlantic Coast of Maryland Shoreline Protection Project (Atlantic Coast Project). The SEIS evaluated new borrow sources to provide sand for routine periodic beach nourishment of Ocean City, MD, for the years 2010–2044. Existing borrow sources in state waters are anticipated to be exhausted after about 2010.

Between 6,800,000 and 15,000,000 cubic yards of sand would be needed through 2044, depending on future storm frequency and intensity. Three offshore shoals in Federal waters are proposed as sand sources: Weaver, Isle of Wight, and ''A.'' Sand may also be dredged from Shoal ''B,'' also known as Bass Grounds or First Lump, in the future, but only if its value as a fishing ground declines substantially. Guidelines to minimize long-term impacts to the offshore shoals were formulated in coordination with resource agency personnel and academic experts. Dredging would be conducted in accordance with these guidelines. Specific dredging plans would be developed in coordination with resource agencies prior to each beach nourishment cycle.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Spaur by mail at U.S. Army Corps of Engineers, Baltimore District, Attn: Mr. Christopher Spaur, CENAB–PL–P, P.O. Box 1715, Baltimore, MD 21203–1715; or electronically at *christopher.c.spaur@usace.army.mil*, or by telephone at (410) 962–6134 or (800) 295–1610.

SUPPLEMENTARY INFORMATION: The Atlantic Coast Project is designed to provide coastal flood and erosion protection to Ocean City, MD against a 100-year storm on the Atlantic Ocean. The *Atlantic Coast of Maryland and Assateague Island Virginia Feasibility Report and Final Environmental Impact Statement* for the project was finalized in August 1980. Subsequent environmental documents were prepared for the project in 1989 (*Atlantic Coast of Maryland Hurricane Protection Project Final General Design Memorandum, Book 1 Main Report and Environmental Assessment*) and 1993 (*Environmental Assessment for the Use of Borrow Area No. 9 as Part of the Periodic Renourishment and Maintenance of the Atlantic Coast of Maryland Shoreline Protection Project*). The project was completed in 1994. Periodic nourishment and maintenance of the beach are required to maintain the design level of protection. Since 1998, a period of few severe storms, approximately 800,000 cubic yards of sand have been placed on Ocean City beach every four years.

This Final SEIS documents findings of investigations conducted to select new borrow sources for the Atlantic Coast Project through the remainder of the project's 50 year economic life. Studies to develop the borrow plan were conducted by USACE in partnership with the Maryland Department of Natural Resources (DNR), Minerals Management Service (MMS), Ocean City, and Worcester County. DNR is the cost-sharing non-Federal sponsor of the study with USACE; MMS is a cooperating agency. A Notice of Intent (NOI) to prepare a General Reevaluation Report and Supplemental Environmental Impact Statement was published in the **Federal Register** on October 21, 2003 (68 FR 60095). Coordination with resource agency personnel, academic experts, and fishermen was undertaken during plan formulation. The USEPA listed the draft SEIS among its weekly receipts in the **Federal Register** on July 6, 2007 (72 FR 37006). An NOA was published in the **Federal Register** on July 10, 2007 (72 FR 37518) by the Department of the Army announcing release of the draft SEIS for public and agency review. The comment period closed August 28, 2007. A public meeting for the draft SEIS was held in Ocean City on July 25th, 2007. Written and oral comments were received from resource agencies and the public. Principal among the agency comments concerned potential impacts on Assateague Island. Revisions were made to the draft SEIS to provide additional information to address these comments, as well as provide updates and correct minor information omissions. A summary of these revisions is provided in the final SEIS.

Offshore shoals are the most appropriate sand sources for the project since these contain large quantities of suitable sand that can be cost-effectively obtained. Offshore shoal borrow sources in Federal waters that could provide up to 15,000,000 cubic yards of sand through 2044 were sought and identified. Three offshore shoals were selected and proposed as sand sources based on engineering, environmental, and economic screening criteria: Weaver, Isle of Wight, and ''A.'' Sand at Shoal ''B,'' also known as Bass Grounds or First Lump is engineeringly and economically suitable, however that shoal is currently an important fishing ground. Accordingly, Shoal ''B'' would not be utilized unless future reevaluation finds that its relative value as a fishing ground has declined substantially. Sub-areas on each shoal

were delineated based on suitability of sand for beach nourishment purposes.

Dredging guidelines to minimize long-term impacts to the offshore shoals were formulated. No more than about 5% of the total volume of any shoal would be dredged. Dredging on any given shoal would avoid the crest, be conducted uniformly over a wide area, go no deeper than ambient seafloor depths, and preferentially dredge on the up and downdrift ends of the shoal if suitable sand is present there.

This Final SEIS documents the National Environmental Policy Act (NEPA) compliance for the proposed new offshore shoal borrow sources and supplements previous environmental documents. Printed and electronic copies of the Final SEIS can be obtained from Christopher Spaur. You may view the Final SEIS and related information on the worldwide web at: *http://www.nab.usace.army.mil/PN/CivilWorks.htm*.

The Final SEIS has been prepared in accordance with (1) The National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), and (3) USACE regulations for implementing NEPA (ER–200–2–2).

Christopher C. Spaur,

Ecologist.

[FR Doc. E8–20720 Filed 9–5–08; 8:45 am]

BILLING CODE 3710–41–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement for Shoreline Protection for Flagler County, FL

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD. *Cooperating Agency:* City of Flagler Beach, Flagler Beach, Florida.

ACTION: Notice of intent.

SUMMARY: The Jacksonville District, U.S. Army Corps (Corps) of Engineers intends to prepare a Draft Environmental Impact Statement (EIS) for protection of 18-Miles of coastal shoreline in Flagler County, FL. The project is a cooperative effort between the U.S. Army Corps of Engineers (lead Federal agency) and City of Flagler Beach (non-Federal sponsor and cooperating agency).

ADDRESSES: Ms. C. L. Brooks, U.S. Army Corps of Engineers, Jacksonville District, Planning Division, Environmental Section, P.O. Box 4970, Jacksonville, FL 32207.

FOR FURTHER INFORMATION CONTACT: C. L. Brooks at (904) 232–2130.

SUPPLEMENTARY INFORMATION: Authority for the proposed study is House Resolution 2676 adopted May 22, 2002. A Reconnaissance Report completed in March 2004 by the Corps, concluded based on preliminary findings, there was a federal interest in pursuing shoreline protection for Flagler County, FL.

Alternatives: Project's alternatives include no action and various levels of protection along approximately 18 miles of coastal shoreline with substantial critically eroded areas. In addition to various levels of beach nourishment and periodic renourishment, the Corps will consider other management measures such as nearshore placement of sand, breakwaters, submerged artificial reef, groins, revetments, seawalls, dunes/vegetation, change to the Coastal Construction Control Line, relocation of structures, moratorium on construction, establish a no-growth program, relocation of structures, flood proofing of structures, and condemnation of structures with land acquisition.

Issues: The EIS will consider impacts on hardbottom communities, sea grasses, protected species, shore impacts, health and safety, water quality, aesthetics and recreation, fish and wildlife resources, cultural resources, energy conservation, socio-economic resources, navigation, and other impacts identified through scoping, public involvement and interagency coordination.

Scoping: The scoping process will involve Federal, State, County and municipal agencies and other interested persons and organizations. Any public or agency scoping meeting will be announced separately from this notice.

Public Involvement: We invite the participation of affected Federal, State and local agencies, affected Native-American Tribes, and other interested private organizations and individuals. There will be a public meeting on the Draft Environmental Impact Statement following its preparation. The date, time, and location will be announced.

Coordination: The proposed action is being coordinated with the U.S. Fish and Wildlife Service (FWS) [under Section 7 of the Endangered Species Act and the Fish and Wildlife and Coordination Act] and with the National Marine Fisheries Service [under the Magnuson-Stevens Fishery Conservation and Management Act (on Essential Fish Habitat) and Section 7 of the Endangered Species Act]. The proposed action is also being coordinated with the Florida State Historic Preservation Officer, the U.S. Coast Guard, and the U.S. Environmental Protection Agency.

Other Environmental Review and Consultation: The proposed action would involve evaluation for compliance with guidelines pursuant to Section 404(b)(1) of the Clean Water Act, water quality certification (application to the State of Florida) pursuant to Section 401 of the Clean Water Act, certification of state lands, easements, and rights-of-way, and determination of Coastal Zone Management Act Consistency.

Agency Role: As the cooperating agency, non-Federal sponsor and leading local expert, the City of Flagler Beach will provide information and assistance on the resources to be impacted, mitigation measures and alternatives. Other agencies having either regulatory authority or special expertise may also be invited to become a cooperating agency in preparation of the EIS.

Draft EIS Preparation: It is anticipated that the Draft EIS will be available to the public by December 2010. As the study and EIS develop, additional information will be posted under Flagler County on the Jacksonville District's Environmental Documents Web page at: *http://planning.saj.usace.army.mil/envdocs/envdocsb.htm.* The status of any Florida Department of Environmental Protection application submitted for permit of this action will be posted on the Internet at: *http://www.dep.state.fl.us/beaches/permitting/permits.htm.*

Dated: August 26, 2008.

Eric P. Summa,

Acting Chief, Environmental Branch.

[FR Doc. E8–20722 Filed 9–5–08; 8:45 am]

BILLING CODE 3710–AJ–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Missouri River Recovery Implementation Committee; Meeting

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of meeting.

SUMMARY: In accordance with Section 5018 (b) of the Water Resources Act of 2007, announcement is made of the following committee meeting:

Name of Committee: Missouri River Recovery Implementation Committee.

Date: September 29–October 1, 2008.

Time: 1 p.m. to 6 p.m. (September 29, 2008). 8:30 a.m. to 6 p.m. (September 30, 2008). 8:30 a.m. to 6 p.m. (October 1, 2008).

Place: Sheraton Clayton Plaza Hotel, 7730 Bonhomme Avenue, Clayton, MO 63105.

FOR FURTHER INFORMATION CONTACT: Mary Roth, U.S. Army Corps of Engineers, Northwestern Division, 1616 Capitol Avenue, Suite 365, Omaha, NE 68102–4909.

SUPPLEMENTARY INFORMATION: This will be the first meeting of the Missouri River Recovery Implementation Committee (Committee). Members of the public may attend the meeting in person. Seating is limited and is available on a first-come, first-served basis. Participation by the public is scheduled for 5 p.m.–5:30 p.m. each day of the meeting.

Proposed Agenda: As the initial meeting of the Committee, the goals of the meeting are to have members meet and get acquainted, and discussion and establishment of: Committee operations, goals, and objectives; roles and responsibilities of members; the need for and makeup of subcommittees; the need for professional facilitation; and schedule, location, topics, and assignments for future meetings. The Committee will also be briefed on: the Missouri River Recovery Program; the Missouri River Ecosystem Restoration Plan; the relationship of the Yellowstone River to recovery of the pallid sturgeon; the similarity of appearance of the shovelnose sturgeon to the pallid sturgeon; and the benefits of collaboration.

Members of the public may make oral comments at the meeting or submit written comments. In general, each individual or group making an oral presentation will be limited to five minutes, and total oral comments will be limited to one-half hour each day. Written comments received far enough in advance of the meeting may be provided to the Committee prior to the meeting; comments received too near the meeting date to allow for distribution will be provided to the Committee at the meeting. Comments submitted during or after the meeting will be accepted but may not be provided to the Committee until after the meeting.

Any member of the public who desires further information concerning the meeting or wishes to submit oral or written comments should contact Mary Roth at the address shown in (see **ADDRESSES**). Requests to make oral comments must be in writing (or by e-mail to *mary.s.roth@usace.army.mil*) and received by Ms. Roth no later than 5 p.m. Central Daylight Time on September 26, 2008.

Dated: August 28, 2008.

Larry L. Murphy,

Acting Chief, Missouri River Water Management, Northwestern Division, U.S. Army Corps of Engineers.

[FR Doc. E8–20721 Filed 9–5–08; 8:45 am]

BILLING CODE 3710–62–P

DELAWARE RIVER BASIN COMMISSION

Notice of Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold an informal conference followed by a public hearing on Wednesday, September 24, 2008. The hearing will be part of the Commission's regular business meeting. Both the conference session and business meeting are open to the public and will be held at the West Trenton Volunteer Fire Company, 40 West Upper Ferry Road, West Trenton, New Jersey.

The conference among the commissioners and staff will begin at 10:30 a.m. Topics of discussion will include: a Decree Parties' report; an annual update on implementation of the 2004 Water Resources Plan for the Delaware River Basin (''Basin Plan''); a report by the chair of the Commission's Water Quality Advisory Committee; a report by the chair of the Commission's Flood Advisory Committee; and a report on the status of development of the Flood Analysis Model, a project commenced in August 2007 at the request of the governors of the four Basin states, in accordance with a recommendation of the Interstate Flood Mitigation Task Force.

The subjects of the public hearing to be held during the 1:30 p.m. business meeting include the dockets listed below:

1. *Burlington Country Club D–67–32–2.* An application for approval of a ground and surface water withdrawal project to supply up to 3.1 million gallons per thirty days (mg/30 days) from new Wells Nos. 1A, 1R and C1, and to supply 8.4 mg/30 days from one new and one existing surface water intake for the applicant's golf course irrigation system. The withdrawal from all sources is proposed to be limited to 8.4 mg/30 days and 37.8 mg/year. The project is located in the Englishtown Formation in the Lower Delaware Watershed in Westampton Township, Burlington County, New Jersey.

2. *Perkasie Borough Authority D–97–12 CP–3.* An application for approval of a ground water withdrawal project to supply up to 11.67 million gallons per 30 days (mg/30 days) of water to the applicant's distribution system from new Well No. 7 in the Brunswick Formation and to retain the existing withdrawal from all wells at 40.2 mg/30 days. Proposed Well No. 7 will be used to replace some of the ground water supply from Perkasie Borough Authority's existing wells that may be lost due to regulatory changes limiting the concentration of arsenic in public drinking water supply. The project is located in the Three Mile Run and East Branch Perkiomen Creek Watersheds in Perkasie Borough, Bucks County, Pennsylvania, within the Southeastern Ground Water Protected Area.

3. *Floyd G. Hersh, Inc. D–98–7–2.* An application for the renewal of a ground water withdrawal project to continue withdrawal of 3.750 mg/30 days to supply the applicant's golf course irrigation system from existing Well No. PW–1 in the Brunswick Formation. The project is located in the Perkiomen—Macoby Creek Watershed in Marlborough Township, Montgomery County, Pennsylvania and is located in the Southeastern Pennsylvania Ground Water Protected Area.

4. *Mercer County Improvement Authority d/b/a Mercer Oaks Golf Course D–99–28 CP–2.* An application for renewal of an existing surface water intake and approval of two new ground water wells for golf course irrigation and to retain the existing withdrawal from all sources of 15 mg/30 days. The project is located in the Potomac-Raritan-Magothy Aquifer in the Assunpink Creek Watershed in West Windsor Township, Mercer County, New Jersey.

5. *Washington Township Municipal Utilities Authority D–99–43 CP–2.* An application for the renewal of a ground water withdrawal project to change existing Well No. 20 from an Aquifer Storage and Recovery well to a production well, to continue the total combined withdrawal of 273.01 mg/30 days from all fifteen wells, and to increase the allocation for Wells Nos. 2, 3, 4, 5, 8, 9, 15 and 20 from 109 mg/30 days to 133.81 mg/30 days to supply the applicant's public supply distribution system from existing Wells Nos. 2, 3, 4, 5, 8, 9, 10, 11, 14, 15, 16, 17, 18, 19, and 20 in the Mt. Laurel-Wenonah and Kirkwood-Cohansey Formations. The project is located in the Big Timber Creek and Mantua Creek watersheds in

Washington Township, Gloucester County, New Jersey.

6. *Lehigh County Authority D–2001–20 CP–3.* An application to replace the withdrawal of water from Well No. WL–8 in the applicant's water supply system that has become an unreliable source of supply. The applicant requests that the withdrawal from replacement Well No. WL–8 be limited to 56.16 mg/30 days of water, and that the total withdrawal from all wells remain limited to 256.24 mg/30 days. The project is located in the Allentown Formation in the Little Lehigh Creek Watershed in Upper Macungie Township, Lehigh County, Pennsylvania. The site is located within the drainage area to the section of the non-tidal Delaware River known as the Lower Delaware, which is designated as Special Protection Waters.

7. *Ambler Borough Water Department D–85–26 CP–4.* An application for approval of a ground water withdrawal project to supply up to 4.75 mg/30 days of water to the applicant's public water supply distribution system from new Well No. 15 and to increase the existing withdrawal from all wells of 116 mg/30 days to 120.75 mg/30 days. The project is located in the Stockton Formation in the Wissahickon Creek Watershed in Lower Gwynedd and Upper Dublin Townships, Montgomery County, Pennsylvania, within the Southeastern Pennsylvania Ground Water Protected Area. The DRBC has recommended a reduction in the docket holder's allocation from 116 mg/30 days to 90 mg/30 days.

8. *Croda, Inc., Docket No. D–88–74–3.* An application for the renewal of a ground and surface water withdrawal project to increase withdrawal from 60.04 mg/30 days to 76.63 mg/30 days from existing Wells Nos. 8, 9, 10, 11, and 12 and to retain the existing allocation of 470.59 mg/30 days from Intake 1 to supply the applicant's industrial facility. The project ground water withdrawals are located in the Potomac Formation, in the Brandywine-Christina Watershed. The project surface water withdrawal is located on the west bank of the Delaware River, in Zone 5. The project is located south of Interstate Route 295 in New Castle County, Delaware. The DRBC has recommended a reduction in the docket holder's surface water withdrawal from 470.59 mg/30 days to 99.0 mg/30 days.

9. *Concord Township Sewer Authority D–97–19 CP–2.* An application to expand the 1.2 million gallon per day (mgd) Central sewage treatment plant (STP) to process 1.8 mgd, while continuing to provide tertiary treatment prior to discharging to West Branch Chester Creek in non-tidal waters. The Central STP is located off the intersection of Conchester Road (Route 322) and Baltimore Pike (Route 1) in Concord Township, Delaware County, Pennsylvania. The STP will continue primarily to serve Concord Township, but it also will serve small portions of Thornbury and Chester Heights Townships, also in Delaware County, Pennsylvania.

10. *DS Waters of America and Nestlé Waters North America Inc. D–97–46–3.* An application for the renewal of a spring water withdrawal project to continue withdrawal of 9.0 mg/30 days to supply the Applicant's spring water bottling facility from existing Spring Nos. 1 and 3 in the Tulpehocken Creek Watershed, in the Richland and Leithsville Formations, in Millcreek Township, Lebanon County, Pennsylvania. Additionally, Nestlé Waters North America Inc. has requested consideration for them to become a joint docket holder and they are proposing to change the exportation site of the 0.300 mgd of water from West Earl Township, Lancaster County, Pennsylvania to their site in Breinigsville, Lehigh County, Pennsylvania.

11. *Upper Uwchlan Township D–2000–55 CP–2.* An application for the approval of the expansion and modification to the existing Upper Uwchlan Township Route 100 Regional Wastewater Treatment Plant (WWTP) from 0.3 mgd to 0.6 mgd. The WWTP is located in Upper Uwchlan Township, Chester County, Pennsylvania. The WWTP will serve existing and proposed development along the Route 100 corridor in Upper Uwchlan Township, Chester County, Pennsylvania. The WWTP will discharge treated effluent to open space in new subdivisions being developed in the service area, in both the Pickering Creek and Marsh Creek watersheds, using both drip dispersal and spray irrigation.

12. *Tidewater Utilities, Inc. D–2005–26 CP–2.* An application for the renewal of a ground water withdrawal project to increase withdrawal from 3.85 mg/30 days to 29.458 mg/30 days to supply the applicant's North Dover and Garrisons Lake public supply distribution systems from existing Wells Nos. SF–01, SF–02 and KWE–02 in the Federalsburg and Cheswold Formations and new Wells Nos. 154547, 71057, 71058, 192844 and 109193 in the Cheswold and Piney Point Formations. The increased allocation is requested in order to interconnect formerly independent service districts and to meet projected increases in service area demand. The project is located in the Leipsic River Watershed in Kent County, Delaware.

13. *UMH Properties, Inc. D–2007–22–1.* An application for approval of a ground water withdrawal project to supply up to 6 mg/30 days of water to the applicant's Fairview Manor Mobile Home Park from new Wells Nos. 1 and 2 and to limit the existing withdrawal from all wells to 6 mg/30 days. The project is located in the Coastal Plains Aquifer in the Cohansey Watershed in Vineland City, Cumberland County, New Jersey.

14. *Venice One Development D–2007–30–1.* An application for the approval of the Venice One Development, which consists of four 6-story buildings comprising a total of 280 residential units and appurtenant ground level parking, both under and adjacent to the buildings, to be constructed on Venice Island, in the Manayunk Section of the City of Philadelphia, Pennsylvania. Under DRBC's *Flood Plain Regulations*, the Venice One Development is reviewable as a Class II project. Class II projects include any development of land—whether residential or non-residential—within a flood hazard area located in a non-tidal area of the basin, which contains more than 25 dwelling units or includes one or more structures covering a total land area of more than 50,000 square feet. The Venice One Development is to be constructed on Venice Island, which is located in the flood fringe portion of the flood hazard area. A flood hazard area is defined by DRBC FPR as the area inundated by a regulatory flood (100-year floodplain).

15. *Waterford Apartments At Cotton Street Development D–2007–36–1.* An application for the approval of the Waterford Development, which consists of one four-story building comprising a total of 205 residential units and appurtenant ground level parking, both under and adjacent to the buildings, to be constructed on Venice Island, in the Manayunk Section of the City of Philadelphia, Pennsylvania. Under DRBC's Flood Plain Regulations, the Waterford Development is reviewable as a Class II project. Class II projects include any development of land—whether residential or non-residential—within a flood hazard area located in a non-tidal area of the basin, which contains more than 25 dwelling units, or includes one or more structures covering a total land area of more than 50,000 square feet. The Waterford Apartment Project is to be constructed on Venice Island, which is located in the flood fringe portion of the flood hazard area. A flood hazard area is defined by DRBC FPR as the area inundated by a regulatory flood (100-year floodplain).

16. *Pennsylvania American Water Company D–2008–2–1.* An application for approval of the existing Yardley water treatment plant's 0.402 mgd backwash discharge to an unnamed tributary to Brock Creek. The water treatment plant discharges filter backwash and sludge filter press filtrate to the section of the non-tidal Delaware River known as the Lower Delaware, which is designated as Special Protection Waters. The facility is located in Yardley Borough, Bucks County, Pennsylvania.

17. *Fralinger Farms D–2008–16–1.* An application for the approval of a ground water withdrawal project to supply a maximum of 78.6 mg/30 days of water to the applicant's irrigation system for approximately 283 acres of fruit trees. The applicant's 15 wells are located in the Kirkwood-Cohansey Formation in the Cohansey River Watershed in Hopewell Township, Cumberland County, New Jersey. The DRBC has recommended a reduction in the docket holder's allocation from 78.6 mg/30 days to 18.75 mg/30 days.

The business meeting also will include adoption of the Minutes of the Commission's July 16, 2008 business meeting; announcements of upcoming advisory committee meetings and other events; a report on hydrologic conditions in the basin; a report by the Executive Director; and a report by the Commission's General Counsel. The meeting will include consideration by the Commission of a resolution amending the Water Code and Comprehensive Plan to implement a Flexible Flow Management Program for the New York City Delaware Basin Reservoirs. The Commission issued a notice of proposed rulemaking on these amendments on December 3, 2007. It announced it would accept comments on the proposed changes through January 18, 2008, a date that was later extended to March 3. It held a hearing on the proposed amendments on January 16, 2008. No hearing on this matter will take place on September 24. If the Commission approves the amendments, a detailed comment and response document will be issued upon filing of the amendments with each of the signatory parties in accordance with Section 14.2 of the Delaware River Basin Compact. The amendments cannot go into effect without the unanimous consent of the parties to the 1954 Supreme Court decree in *New Jersey* v. *New York*, 347 U.S. 995 (1954). Also during the business meeting, the Commission will hold a public hearing on a resolution amending the composition of the Water Quality Advisory Committee to add members from the environmental and academic sectors and a resolution authorizing the executive director to enter into an agreement for a sediment flux study of mercury in Water Quality Zone 5. It will consider a resolution authorizing the executive director to extend the Commission's 2002 agreement with Axys Analytical Services Ltd. for sampling and analysis of toxic substances in ambient water, wastewater and sediment samples from the Delaware Estuary. An opportunity for public dialogue will be provided at the end of the meeting.

Draft dockets scheduled for public hearing on September 24, 2008 will be posted on the Commission's Web site, *http://www.drbc.net,* where they can be accessed through the Notice of Commission Meeting and Public Hearing. Additional documents relating to the dockets and other items may be examined at the Commission's offices. Please contact William Muszynski at 609–883–9500, extension 221, with any docket-related questions.

Individuals in need of an accommodation as provided for in the Americans with Disabilities Act who wish to attend the informational meeting, conference session or hearings should contact the commission secretary directly at 609–883–9500 ext. 203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how the Commission can accommodate your needs.

Dated: September 2, 2008.

Pamela M. Bush,

Commission Secretary.

[FR Doc. E8–20700 Filed 9–5–08; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2145–088]

Public Utility District No. 1 of Chelan County; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

August 29, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Change in Project Land Rights, and Project Boundary.

b. *Project No.* 2145–088.

c. *Date Filed:* July 14, 2008.

d. *Applicant:* Public Utility District No. 1 of Chelan County.

e. *Name of Project:* Rocky Reach Hydroelectric Project.

f. *Location:* The project is located on the Columbia River in Chelan County, Washington. Specifically, the area of the project related to this application is located on the west side of the Columbia River about 39 miles upstream of Rocky Reach Dam and three miles south of Wells Hydroelectric Project.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Michelle Smith, License and Natural Resource Compliance Manager, Public Utility District No. 1 of Chelan County, P.O. Box 1231, Wenatchee, WA 98807–1231. Phone: (888) 663–8121, Ext. 4180.

i. *FERC Contact:* Any questions on this notice should be addressed to Brian Romanek at (202) 502–6175, or by e-mail: *Brian.Romanek@ferc.gov*.

j. Deadline for filing comments, motions to intervene, and protests: October 2, 2008.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the applicant specified in the particular application.

k. *Description of the Application:* The applicant is seeking Commission authorization to convey ownership of 0.7 acre of project land to Goodfellow Living Trust (Trust) in exchange for flowage rights on 2.37 acres of land at a nearby site along the shoreline. The acquired flowage easement land would be enclosed within the project boundary and the land conveyed to the Trust would be removed from the project.

l. *Location of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket

number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments*—Federal, State, and local agencies are invited to file comments on the application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20710 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–465–000]

ANR Pipeline Company; Notice of Application

August 29, 2008.

Take notice that on August 20, 2008, ANR Pipeline Company (ANR), 717 Texas Street, Houston, Texas 77002, filed in Docket No. CP08–465–000 an application pursuant to section 7(c) of the Natural Gas Act (NGA) and the Commission's Regulations, for authorization to construct and operate certain facilities referred to as its Wisconsin Expansion Project 2009 in various Wisconsin counties, as more fully set forth in the application which is open to the public for inspection. This filing may be also viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERCOnline Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

ANR proposes to: (1) Construct and operate approximately 8.9 miles of 30-inch diameter pipeline looping on its Madison lateral in Rock County; (2) install one mainline control valve each at the Marshfield compressor station in Wood County and at the Fairwater meter station in Columbia County; and (3) upgrade minor facilities at the Marshfield meter station in Wood County, the North Wausau meter station in Marathon County, and the Randolph meter station in Columbia County. ANR states that the proposed new facilities would allow ANR to provide approximately 97,880 Dekatherm equivalent of natural gas per day in new firm transportation capacity in Wisconsin. ANR also states that the proposed Wisconsin Expansion Project 2009 facilities would cost approximately $38,259,931 to construct.

Any questions regarding this application should be directed to Dean Ferguson, Vice President, Marketing and Business Development, ANR Pipeline Company, 717 Texas Street, Houston, Texas 77002, or by telephone at (832) 320–5703, facsimile at (832) 320–5704 or via e-mail: *dean_ferguson@transcanada.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Comment Date: September 19, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20711 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2145–087]

Public Utility District No. 1 of Chelan County; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, And Protests

August 29, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Change in Project Land Rights and Project Boundary.

b. *Project No.:* 2145–087.

c. *Date Filed:* June 6, 2008 and supplemented on July 16, 2008.

d. *Applicant:* Public Utility District No. 1 of Chelan County.

e. *Name of Project:* Rocky Reach Hydroelectric Project.

f. *Location:* The project is located on the Columbia River in Chelan County, Washington. Specifically, at Entiat Park.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r)

h. *Applicant Contact:* Michelle Smith, License and Natural Resource Compliance Manager, Public Utility District No. 1 of Chelan County, P.O. Box 1231, Wenatchee, WA 98807–1231. Phone: (888) 663–8121, Ext. 4180.

i. *FERC Contact:* Any questions on this notice should be addressed to Brian Romanek at (202) 502–6175, or by e-mail: *Brian.Romanek@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* October 2, 2008

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the applicant specified in the particular application.

k. *Description of the Application:* The applicant is seeking Commission authorization for an exchange of 0.5 acre of project land, owned by the licensee, for 8.53 acres owned by the City of Entiat (City). The parcel the licensee would acquire is located between two parcels of parkland (Entiat Park) owned by the licensee. This land exchange would allow the licensee to own the entire park. The park is a part of the project's approved recreation plan and is enclosed within the project boundary. The 0.5 acres to be conveyed to the City would be removed from the project boundary.

l. *Location of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20716 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER08–1442–000]

Flat Ridge Wind Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

August 29, 2008.

This is a supplemental notice in the above-referenced proceeding of Flat Ridge Wind Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is September 19, 2008.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the

FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20714 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

September 2, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP08–552–000.

Applicants: Columbia Gulf Transmission Company.

Description: Columbia Gulf Transmission Company submits Forty-Sixth Revised Sheet 18 *et al.* to FERC Gas Tariff, Second Revised Volume 1, to be effective 10/1/08.

Filed Date: 08/28/2008.

Accession Number: 20080829–0088.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–553–000.

Applicants: Central Kentucky Transmission Company.

Description: Central Kentucky Transmission Company submits Sixth Revised Sheet 6 to FERC Gas Tariff, Second Revised Volume 1, to be effective 10/1/08.

Filed Date: 08/28/2008.

Accession Number: 20080829–0099.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–554–000.

Applicants: Crossroads Pipeline Company.

Description: Crossroads Pipeline Co. submits Ninth Revised Sheet 6 to FERC Gas Tariff, Second Revised Volume 1, to be effective 10/01/2008.

Filed Date: 08/28/2008.

Accession Number: 20080829–0089.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–555–000.

Applicants: Columbia Gas Transmission Corporation.

Description: Columbia Gas Transmission Corp submits Eighty-Eight Revised Sheet 25 *et al.* to FERC Gas Tariff, Second Revised Volume 1 to be effective 10/01/2008.

Filed Date: 08/28/2008.

Accession Number: 20080829–0090.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–556–000.

Applicants: Great Lakes Gas Transmission Limited Partnership.

Description: Great Lakes Gas Transmission Limited Partnership submits a filing to reflect the $.00170 per Dth charge required under the Annual Charges Adjustment of Order 472, effective 10/1/08.

Filed Date: 08/28/2008.

Accession Number: 20080829–0091.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–557–000.

Applicants: Granite State Gas Transmission, Inc.

Description: Granite State Gas Transmission Inc submits Thirty-third Revised Sheet 21 *et al.* to FERC Gas Tariff, Second Revised Volume 1, to be effective 10/1/08.

Filed Date: 08/28/2008.

Accession Number: 20080829–0092.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 9, 2008.

Docket Numbers: RP08–558–000.

Applicants: Northwest Pipeline GP.

Description: Northwest Pipeline GP submits First Revised Sheet 5 *et al.* to FERC Gas Tariff, Fourth Revised Volume 1.

Filed Date: 08/26/2008.

Accession Number: 20080829–0112.

Comment Date: 5 p.m. Eastern Time on Monday, September 8, 2008.

Docket Numbers: RP08–559–000.

Applicants: Williston Basin Interstate Pipeline Co.

Description: Williston Basin Interstate Pipeline Co. Annual Report of Penalty Revenue Credits.

Filed Date: 08/29/2008.

Accession Number: 20080829–5012.

Comment Date: 5 p.m. Eastern Time on Wednesday, September 10, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–20620 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–441–000; Docket No. CP07–444–000]

Pacific Connector Gas Pipeline, LP, Jordan Cove Energy Project, LP; Notice of Availability of the Draft Environmental Impact Statement for the Proposed Jordan Cove LNG and Pacific Connector Gas Pipeline Project

August 29, 2008.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft Environmental Impact Statement (EIS) for the construction and operation of the liquefied natural gas (LNG) import terminal and natural gas pipeline facilities proposed by Jordan Cove Energy Project, LP (Jordan Cove) and Pacific Connector Gas Pipeline LP (Pacific Connector) in the above-referenced dockets. We [1] call this the Jordan Cove Energy and Pacific Connector Pipeline (JCE & PCGP) Project, or simply the Project. The JCE & PCGP Project facilities would be located in Coos, Douglas, Jackson, and Klamath Counties, Oregon.

The draft EIS was prepared to satisfy the requirements of the National Environmental Policy Act. The United States (U.S.) Department of Agriculture Forest Service, U.S. Army Corps of Engineers, U.S. Environmental Protection Agency, U.S. Department of Homeland Security Coast Guard, Pipeline and Hazardous Materials Safety Administration of the U.S. Department of Transportation, U.S. Department of the Interior Bureau of Land Management and Bureau of Reclamation, and Douglas County, Oregon, are cooperating agencies for the development of this EIS. A cooperating agency has jurisdiction by law or special expertise with respect to potential environmental impacts associated with the proposal and is involved in the NEPA analysis.

Based on the analysis included in the draft EIS, the FERC staff concludes that the proposed action would have limited adverse environmental impacts. However, if the Project is constructed and operated in accordance with applicable laws and regulations, and with implementation of Jordan Cove's and Pacific Connector's proposed mitigation measures, and the additional mitigation measures recommended by staff, environmental impacts would be substantially reduced.

The purpose of the Project is to provide a new import access point for overseas LNG and provide a new source of natural gas to markets in the Pacific Northwest, northern Nevada, and northern California. LNG is natural gas that has been turned into a liquid state by cooling it to about −260 degrees Fahrenheit to reduce its volume for transport in specially designed carriers some distance across oceans from its point of origin to the proposed Jordan Cove LNG import terminal in Coos Bay. Jordan Cove would off-load and would store the LNG in specially designed tanks at its terminal, vaporize the LNG back into natural gas, and provide up to 1.0 billion cubic feet per day of natural gas to the region through the Pacific Connector sendout pipeline and interconnections with an intrastate pipeline, and four interstate pipeline systems.

The draft EIS addresses the potential environmental effects associated with the construction and operation of the facilities listed below. Jordan Cove's import terminal, located on the bay side of the North Spit of Coos Bay, at about Channel Mile 7.5 up the existing Coos Bay navigation channel, in Coos County, Oregon, would include:

- Access channel from the existing Coos Bay navigation channel and slip;
- LNG unloading berth and transfer pipeline;
- Two full-containment LNG storage tanks, each with a capacity 160,000 m^3 (or 1,006,000 barrels);
- Vapor handling system, and vaporization equipment capable of regasifying the LNG for delivery into the natural gas sendout pipeline;
- Piping, ancillary buildings, safety systems, and other support facilities;
- A natural gas liquids (NGL) extraction facility, with the NGL to be sold to an entity other than Jordan Cove and likely transported from the terminal using existing railroad lines;
- 37-megawatt, natural gas-fired, simple-cycle combustion turbine powerplant to provide electric power for the LNG terminal; and
- Three disposal areas for the storage of excavated and dredged materials resulting from the construction of the access channel and slip.

Pacific Connector's natural gas facilities, extending from the Jordan Cove terminal southeast across Coos, Douglas, Jackson, and Klamath Counties Oregon, to its terminus near Malin, with interconnections with Avista Corporation, Williams Northwest Pipeline Corporation (Williams Northwest), Gas Transmission Northwest Corporation, Tuscarora Gas Transmission Company, and Pacific Gas and Electric Company, would include:

- 229.5-mile-long, 36-inch-diameter welded steel underground interstate natural gas pipeline;
- Natural gas compressor station at Butte Falls, in Jackson County, consisting of two new 10,310-horsepower (hp) compressor units;
- Four natural gas meter stations, including the Jordan Cove Receipt Meter Station in Coos County, Clarks Branch Delivery Meter Station in Douglas County, Shady Cove Delivery Meter Station in Jackson County, and the adjoining Tule Lake, Russell Canyon, and Buck Butte Meter Stations in Klamath County;
- Gas control communication system, consisting of new radio towers at each meter station and the compressor station, use of an existing communication site owned by Williams Northwest and leased space on seven other existing communication towers;
- Mainline block valves (MLV) at approximately 16 locations along the Pacific Connector pipeline; and
- Five pig [2] launchers and receivers, four co-located with meter stations and the compressor station, and the fifth co-located with a MLV.

Comment Procedures

Any person wishing to comment on the draft EIS may do so. To ensure consideration prior to the Commission making a decision on the proposals, it is important that the Commission receives your comments before December 4, 2008. Please carefully follow the instructions below so that your comments are properly recorded.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances please reference the Project Docket Numbers CP07–441–000 and CP07–444–000 with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at 202–502–8258 or *efiling@ferc.gov*.

(1) You may file your comments electronically by using the Quick Comment feature, which is located on the Commission's internet Web site at *http://www.ferc.gov* under the link to Documents and Filings. A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the eFiling

[1] The pronouns "we," "us," or "our" refer to the environmental staff of the FERC's Office of Energy Projects.

[2] A "pig" is a tool for cleaning and inspecting the inside of a pipeline.

feature, which is located on the Commission's internet Web site at *http://www.ferc.gov* under the link to Documents and Filings. eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file as your submission. New eFiling users must first create an account by clicking on ''Sign up'' or ''eRegister.'' You will be asked to select the type of filing you are making. A comment on a particular project is considered a ''Comment on a Filing''; or

(3) You may file your comments via mail to the Commission by sending an original and two copies of your letter to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First St., NE, Room 1A, Washington, DC 20426.

Label one copy of the comments for the attention of Gas Branch 3, PJ–11.3. Mail your comments promptly, so that they will be received in Washington, DC on or before December 4, 2008.

In addition to receiving written comments, by mail or electronically, we will hold a series of public meetings at several locations near the Project area in southwestern Oregon to take oral comments on the draft EIS. The FERC will issue a notice in the near future providing the dates, time, and locations of these public comment meetings.

After comments on the draft EIS are reviewed, any significant new issues are investigated, and modifications are made to the EIS text, a final EIS will be published and distributed. The final EIS will contain the staff's responses to timely comments received on the draft EIS.

Comments will be considered by the Commission and the cooperating agencies but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Only intervenors have the right to seek rehearing of the Commission's decision. Further instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site (*http://www.ferc.gov*). You do not need intervenor status to have your environmental comments considered.

The draft EIS has been placed in the public files of the FERC and is available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Volumes 1 and 2 of the draft EIS, containing text of the analysis, was printed in hard copy. Volume 3, containing the appendices, was produced as .pdf files on a compact disk (CD) that can be read by a personal computer with a CD–ROM drive. A limited number of hard copies and CDs of the draft EIS are available from the FERC's Public Reference Room, identified above. This draft EIS is also available for public viewing on the FERC's Internet Web site at *http://www.ferc.gov*, via the eLibrary link.

Copies of the draft EIS have been mailed to federal, state, and local agencies; elected officials; Indian tribes and Native American organizations with an interest in the project area; interveners; regional environmental organizations and public interest groups; affected landowners; local libraries and newspapers; and other interested parties. Hard copies of volumes 1 and 2 were mailed to cooperating agencies; other appropriate federal, state, and local government agencies who participated in interagency meetings; intervenors; and parties that specifically requested hard copies. All others on the mailing list were sent a single CD containing all volumes of the draft EIS.

Additional information about the Project is available from the Commission's Office of External Affairs at 1–866–208–FERC (3372) or on the FERC Internet Web site (*http://www.ferc.gov*). Go to Documents & Filings and choose the eLibrary link. Under eLibrary, click on ''General Search,'' and enter the docket number excluding the last three digits in the field (*e.g.*, CP07–441). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at: *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY call 202–502–8659. The eLibrary link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to the eSubscription link on the FERC Internet Web site (*http://www.ferc.gov/esubscripenow.htm*).

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20717 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER08–1439–000]

New Brunswick Power Generation Corporation; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

August 29, 2008.

This is a supplemental notice in the above-referenced proceeding of New Brunswick Power Generation Corporation's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is September 19, 2008.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20713 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER08–1443–000]

Noble Great Plains Windpark, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

August 29, 2008.

This is a supplemental notice in the above-referenced proceeding of Noble Great Plains Windpark, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is September 19, 2008.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20715 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL08–85–000]

California Independent System Operator Corporation; Notice of Institution of Proceeding and Refund Effective Date

April 29, 2008.

On August 29, 2008, the Commission issued an order that instituted a proceeding in Docket No. EL08–85–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2005), to consider the justness and reasonableness of granting the requested waiver of the 60-day notice requirement contained in the original Participating Load Agreement between the California Independent System Operator Corporation and the California Department of Water Resources State Water Project. *California Independent System Operator Corporation*, 124 FERC ¶ 61,205 (2008).

The refund effective date in Docket No. EL08–85–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–20712 Filed 9–5–08; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2008–0573, FRL–8712–2]

Agency Information Collection Activities; Proposed Collection; Comment Request; RCRA Hazardous Waste Permit Application and Modification, Part A, EPA ICR Number 0262.12, OMB Control Number 2050–0034

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on January 31, 2009. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before November 7, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2008–0573, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: rcra-docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* RCRA Docket (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.
- *Hand Delivery:* 1301 Constitution Ave., NW., Room 3334, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–RCRA–2008–0573. 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 *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.*

FOR FURTHER INFORMATION CONTACT: Toshia King, Environmental Protection Agency, Mailcode 5303W, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–7033; fax number: 703–308–8617; e-mail address: *king.toshia@epamail.epa.gov.*

SUPPLEMENTARY INFORMATION:

How Can I Access the Docket and/or Submit Comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–RCRA–2008–0573, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for RCRA Docket is 202–566–0270.

Use *www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What Information Is EPA Particularly Interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What Should I Consider When I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What Information Collection Activity or ICR Does This Apply to?

Affected entities: Entities potentially affected by this action are business or other for-profit, as well as State, local, or Tribal governments.

Title: RCRA Hazardous Waste Permit Application and Modification, Part A

ICR numbers: EPA ICR No. 0262.12, OMB Control No. 2050–0034.

ICR status: This ICR is currently scheduled to expire on January 31, 2009. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 3010 of Subtitle C of RCRA, as amended, requires any person who generates or transports regulated waste or who owns or operates a facility for the treatment, storage, or disposal (TSDF) of regulated waste to notify EPA of their activities, including the location and general description of activities and the regulated wastes managed. Section 3005 of Subtitle C of RCRA requires TSDFs to obtain a permit. To obtain the permit, the TSDF must submit an application describing the facility's operation. There are two parts to the RCRA permit application—Part A and Part B. Part A defines the processes to be used for treatment, storage, and disposal of hazardous wastes; the design capacity of such processes; and the specific hazardous wastes to be handled at the facility. Part B requires detailed site specific information such as geologic, hydrologic, and engineering data.

Burden Statement: The annual public reporting and record keeping burden for this collection of information is estimated to average 25 hours per response for an initial Part A Application and 13 hours per response for a revised Part A application. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information,

processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 23.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.5.

Estimated total annual burden hours: 402 hours.

Estimated total annual costs: $28,884. This includes an estimated burden cost of $28,712 for labor and an estimated cost of $172 for capital investment or maintenance and operational costs.

What is the Next Step in the Process for This ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: August 18, 2008.

Maria P. Vickers,

Acting Director, Office of Solid Waste.

[FR Doc. E8–20723 Filed 9–5–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8712–3]

Notice of Availability of Guidelines for the Award of Alaska Rural and Native Villages Program Grant Authorized by the Clean Water Act and the Consolidated Appropriations Act, 2008

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of a memorandum entitled ''Award of Alaska Rural and Native Villages Program Grant Authorized by the Clean Water Act and the EPA Section of the Consolidated Appropriations Act, 2008'' and the accompanying grant guidelines. These documents describe how EPA will award and administer the 2008 Alaska Rural and Native Villages Program Grant as authorized by Section 113a of the Clean Water Act (33 U.S.C. 1263a) and the Agency's FY 2008 Consolidated Appropriations Act (Pub. L. 110–161). The Consolidated Appropriations Act, 2008, provides budget authority for funding the Alaska Rural and Native Villages Program that assists communities with the rehabilitation or construction of drinking water and wastewater systems and also training and technical assistance in the operations and maintenance of these systems. The grant guidelines will not be reissued annually. The grant recipient, the State of Alaska, will receive a copy of this notice, the memorandum, and a copy of the grant guidelines from EPA.

FOR FURTHER INFORMATION CONTACT: Matthew Richardson, Environmental Protection Specialist, Municipal Support Division, Office of Wastewater Management (4204M), Office of Water, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–2947; fax number: (202) 501–2396; e-mail address: *Richardson.Matthew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action applies to State Agencies, nonprofit institutions, international organizations, and Alaska rural and native villages which are eligible to receive grants from funds included in EPA's State and Tribal Assistance Grants account pursuant to the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) and the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2008.

B. How Can I Get Copies of This Document and Other Related Information?

You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. The associated grant guideline documents may be viewed and downloaded from EPA's Web site at *http://www.epa.gov/owm/mab/indian/anvrs/guidelines.htm.*

Dated: September 2, 2008.

Judy Davis,

Deputy Director, Office of Wastewater Management.

[FR Doc. E8–20731 Filed 9–5–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OEI–2008–0469; FRL–8712–1]

Notification of Deletion of System of Records; OPP Time Accounting Information System (EPA–14)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Privacy Act of 1974, notification of deletion of system of records OPP Time Accounting Information System (EPA–14).

SUMMARY: The Environmental Protection Agency is deleting systems of records *OPP Time Accounting Information System* (EPA–14). Published in the **Federal Register** published on February 22, 2002 (67 FR 8246–8264). Reason for deletion is OPP Time Accounting Information System is being integrated into the PRISM system and the sensitive personally identifiable information has been removed from the TAIS application.

DATES: This notice is effective immediately upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Maryann Petrole, Chief, Financial Management and Planning Branch, Information Technology and Resources Management Division, Office of Pesticide Programs (7502P), Washington, DC 20460, telephone (703) 308–8685.

SUPPLEMENTARY INFORMATION:

I. General Information

How Can I Get Copies of This Document and Other Related Information?

EPA has established a docket for this action under Docket ID No. [EPA–HQ–OEI–2008–0469] copies of the available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

Dated: August 12, 2008.

Molly A. O'Neill,

Assistant Administrator and Chief Information Officer.

[FR Doc. E8–20733 Filed 9–5–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8708–1]

California State Motor Vehicle Pollution Control Standards; Notice of Waiver of Clean Air Act Preemption; California's 2010 Model Year Heavy-Duty Vehicle and Engine On-Board Diagnostic Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice regarding waiver of clean air act preemption.

SUMMARY: By this decision, issued under section 209(b) of the Clean Air Act, as amended, (Act), 42 U.S.C. 7543(b), the Environmental Protection Agency (EPA) is granting California its request for a waiver Clean Air Act preemption for its 2010 and later model year heavy-duty vehicle and engine on-board diagnostic (OBD) requirements.

ADDRESSES: The Agency's Decision Document, containing an explanation of the Deputy Assistant Administrator's decision, as well as all documents relied upon in making that decision, including those submitted to EPA by CARB, are available at EPA's Air and Radiation Docket and Information Center (Air Docket). Materials relevant to this decision are contained in Docket No. EPA–HQ–OAR–2006–0844. The docket is located at the Air Docket, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20460, and may be viewed between 8 a.m. and 5:30 p.m., Monday through Friday. The telephone is (202) 566–1742. A reasonable fee may be charged by EPA for copying docket material.

Additionally, an electronic version of the public docket is available through the Federal government's electronic public docket and comment system. You may access EPA dockets at *http://www.regulations.gov.* After opening the *http://www.regulations.gov* Web site, select ''Environmental Protection Agency'' from the pull-down Agency list, then scroll to ''Keyword or ID'' and enter EPA–HQ–OAR–2006–0844 to view documents in the record of this California request. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Electronic copies of this Notice and the accompanying Decision Document are available via the Internet on the Office of Transportation and Air Quality (OTAQ) Web site and looking at the path entitled *http://www.epa.gov/OTAQ.* Users can find these documents by accessing the OTAQ web and looking at the path entitled **Federal Register** Notices. The electronic **Federal Register** version of the Notice is made available on the day of publication on the primary Web site *http://epa.gov/docs/fedrgstr/EPA-AIR.* Please note that due to the differences between the software used to develop the documents and the software into the documents may be downloaded, changes in format, page length, etc., may occur.

FOR FURTHER INFORMATION CONTACT: David Dickinson, Compliance and Innovative Strategies Division, U.S. Environmental Protection Agency, Ariel Rios Building (6405J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone: (202) 343–9256. *E-Mail Address*: *Dickinson.David@EPA.GOV*

SUPPLEMENTARY INFORMATION: I have decided to grant California a waiver of Clean Air Act preemption pursuant to section 209(b) of the Act for its 2010 and later model year heavy-duty vehicle and engine OBD requirements.[1]

Section 209(b) of the Act provides that, if certain criteria are met, the Administrator shall waive preemption for California to enforce new motor vehicle emission standards and accompanying enforcement procedures. The criteria include consideration of whether California arbitrarily and capriciously determined that its standards are, in the aggregate, at least as protective of public health and welfare as the applicable Federal standards; whether California needs State standards to meet compelling and extraordinary conditions; and whether California's standards are consistent with section 202(a) of the Act.

As further explained in the Decision Document supporting today's decision, although EPA did receive comment on California's request, the Agency finds there is an insufficient basis to deny California its waiver request based on the criteria set forth in section 209(b) of the Act.

In its request letter to EPA, the California Air Resources Board (CARB) stated that the OBD requirements will not cause the California standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards. EPA received no information during this proceeding that questioned whether CARB's OBD requirements are less protective than applicable Federal standards. I cannot find that CARB's OBD regulations would cause the California motor vehicle emission standards, in the aggregate, to be less protective of public health and welfare than applicable Federal standards.

CARB has repeatedly demonstrated, with respect to traditional pollution concerns, (*i.e.* not including global climate change), the existence of compelling and extraordinary conditions in California.[2] EPA has not received any adverse comments to suggest that California no longer suffers from serious and unique air pollution problems. Because EPA has not received adverse public comment, or any other relevant information, challenging the need for CARB's own motor vehicle pollution control program based on lack of compelling and extraordinary conditions for the purposes of this waiver request, I cannotdeny the waiver based on a lack of compelling and extraordinary conditions.

CARB stated in its request letters that the amendments do not raise any concerns of inadequate leadtime or impose any inconsistent certification requirements. EPA received comment suggesting that EPA not necessarily deny the ultimate granting of CARB's waiver request, but rather that EPA defer making a decision in order to ''maximize the opportunities for full alignment and harmonization between the EPA and ARB OBD programs for HDOH engines, and to reduce the prospects that other states will elect to opt into the ARB OBD program, which, from an emissions inventory perspective, will not be materially different from the EPA OBD program.'' EPA notes that its notice of proposed rulemaking for heavy-duty vehicle and engine OBD was published on January 24, 2007 but a final rule has not been completed.[3] Although EPA remains sensitive to the issues raised by the commenter, such comments do not include data or other basis by which to

[1] The CARB Board approved the OBD standards by Resolution 05–38 on July 21, 2005 and the California Office of Administrative Law approved the regulations on February 15, 2006.

[2] EPA recently denied California its request for a waiver for its new motor vehicle greenhouse gas standards. *See* 73 FR 12156 (March 6, 2008).

[3] 72 FR 3200 (January 24, 2007).

demonstrate the feasibility of CARB's OBD requirements. I cannot find that CARB's OBD regulations, as noted, would cause the California motor vehicle emission standards to be inconsistent with section 202(a).

A full explanation of EPA's decision, including our review of comments received, is contained in a Decision Document which may be obtained as explained above.

My decision will affect not only persons in California but also the manufacturers outside the State who must comply with California's requirements in order to produce heavy-duty vehicles and engines for sale in California. For this reason, I hereby determine and find that this is a final action of national applicability.

As with past waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Finally, the Administrator has delegated the authority to make determinations regarding waivers under section 209(b) of the Act to the Assistant Administrator for Air and Radiation.

Dated: August 13, 2008.

Robert J. Meyers,

Principal Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. E8–20732 Filed 9–5–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

August 27, 2008.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection(s). Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before November 7, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: You may submit all PRA comments by e-mail or U.S. post mail. To submit your comments by e-mail, send them to *PRA@fcc.gov.* To submit your comments by U.S. mail, mark them to the attention of Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection(s), contact Cathy Williams at (202) 418–2918 or send an e-mail to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0474.

Title: Section 74.1263, Time of Operation.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for profit entities; not-for-profit institutions.

Number of Respondents/Responses: 75.

Estimated Time per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 38 hours.

Total Annual Costs: None.

Nature of Response: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 154(i), 303 and 308 of the Communications Act of 1934, as amended.

Confidentiality: No need for confidentiality required for this collection of information.

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: 47 CFR 74.1263(c) requires licensees of FM translator or booster stations to notify the Commission of its intent to discontinue operations for 30 or more consecutive days. In addition, licensees must notify the Commission within 48 hours of the station's return to operation. 47 CFR 74.1263(d) requires FM translator or booster station licensees to notify the Commission of its intent to permanently discontinue operations and to forward the station license to the FCC for cancellation. FCC staff uses this data to keep records up-to-date. These notifications inform FCC staff that frequencies are not being used for a specified amount of time and that frequencies have become available for other users.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–20737 Filed 9–5–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

August 26, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated

collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before October 8, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *PRA@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0126.

Title: Section 73.1820, Station Log.

Type of Review: Extension of a currently approved collection.

Form Number: Not applicable.

Respondents: Businesses or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 15,200 respondents; 15,200 responses.

Estimated Time per Response: 0.017–0.5 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 15,095 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR 73.1820 requires that each licensee of an AM, FM or TV broadcast station maintain a station log. Each entry must accurately reflect the station's operation. This log should reflect adjustments to operating parameters for AM stations with directional antennas without an approved sampling system; for all stations the actual time of any observation of extinguishment or improper operation of tower lights; and entry of each test of the Emergency Broadcast System (EBS) for commercial stations.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–20739 Filed 9–5–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collections Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

August 28, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collections, as required by the Paperwork Reduction Act of 1995 (PRA), Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written PRA comments should be submitted on or before November 7, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Interested parties may submit all PRA comments by e-mail or U.S. post mail. To submit your comments by e-mail, send them to *PRA@fcc.gov* and/or *Cathy.Williams@fcc.gov.* To submit your comments by U.S. mail, mark them to the attention of: Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collections, contact Cathy Williams at (202) 418–2918 or send an e-mail to *PRA@fcc.gov* and/or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1047.

Title: Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit entities; State, local or tribal government.

Number of Respondents and Responses: 78 respondents; 209 responses.

Estimated Time per Response: 30 minutes (.50 hours) to 10 hours.

Frequency of Response: Recordkeeping requirement; Annual, on occasion, and one-time reporting requirements.

Total Annual Burden: 766 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority for this collection is contained in sections 1, 2, 4(i), 4(j), 225, 255 and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 225, 255, 303(r).

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On December 12, 2005, the Commission released *Telecommunications Relay Services and Speech-to-Speech Services for*

Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123, Report and Order and Order on Reconsideration, 20 FCC Rcd 20577 (2005) (*2005 TRS Report and Order*), published at 70 FR 76208, December 23, 2005, which created another method for some Telecommunications Relay Service (TRS) providers to become eligible to receive compensation from the Interstate TRS Fund (Fund). Specifically, the *2005 TRS Report and Order* amended the TRS regulations to permit a common carrier seeking to offer Video Relay Service (VRS) or Internet Protocol (IP) Relay Service and receive compensation from the Fund to apply to the Commission for certification as an entity providing these services in compliance with the TRS rules, and therefore eligible to receive reimbursement from the Fund. In a subsequent declaratory ruling, the Commission also permitted entities desiring to provide IP captioned telephone service to seek certification from the Commission for eligibility to receive compensation from the Fund. *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Internet-based Captioned Telephone Service,* CG Docket No. 03–123, Declaratory Ruling, 22 FCC Rcd 379 (2007), published at 72 FR 6960, February 14, 2007.

In order to facilitate this certification process, the Commission adopted information collection requirements that include the following:

(A) 47 CFR 64.606 (a)(2): Providing documentation detailing: (1) A description of the forms of TRS to be provided, (2) a description of how the provider will meet all non-waived mandatory minimum standards applicable to each form of TRS offered, (3) a description of the provider's procedures for ensuring compliance with all applicable TRS rules, (4) a description of the provider's complaint procedures, (5) a narrative describing any areas in which the provider's service will differ from the applicable mandatory minimum standards, (6) a narrative establishing that services that differ from the mandatory minimum standards do not violate applicable mandatory minimum standards, (7) demonstration of status as a common carrier, and (8) a statement that the provider will file annual compliance reports demonstrating continued compliance with the rules;

(B) 47 CFR 64.606 (c)(2): A provider may apply for renewal of its certification by filing documentation with the Commission, at least 90 days prior to expiration of certification, containing the information described in 47 CFR 64.606 (a)(2);

(C) 47 CFR 64.606 (e)(2): A provider must submit documentation demonstrating ongoing compliance with the Commission's minimum standards if, for example, the Commission receives evidence that a certified provider may not be in compliance with the minimum standards and the Commission requests such information;

(D) 47 CFR 64.606 (f)(2): Providers certified under this section must notify the Commission of substantive changes in their TRS programs, services, and features within 60 days of when such changes occur, and must certify that the interstate TRS provider continues to meet federal minimum standards after implementing the substantive change; and

(E) 47 CFR 64.606 (g): Providers certified under this section shall file with the Commission, on an annual basis, a report providing evidence that they are in compliance with 47 CFR 64.604.

In *Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Americans with Disabilities Act of 1990,* CG Docket No. 03–123, CC Docket No. 98–67, Second Report and Order, Order on Reconsideration, and Notice of Proposed Rulemaking, 18 FCC Rcd 12379 (2003), published at 68 FR 50993, August 25, 2003, the Commission adopted additional requirements related to the substance and implementation of TRS mandatory minimum standards. In 47 CFR 64.604(a)(3), the Commission required TRS facilities to provide speed dialing functionality, which may entail providers maintaining a list of telephone numbers. In addition, the Commission bolstered the contact information requirements of 47 CFR 64.604(c)(2).

Furthermore, the Commission required providers receiving waivers of some of these standards to submit to the Commission an annual waiver report that details (1) the technological changes with respect to the functionalities covered by the waivers; (2) the progress made; and (3) the steps taken to resolve the technological problems that prevent these providers from offering certain types of TRS calls and features.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–20741 Filed 9–5–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget, Comments Requested

August 25, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501—3520. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before October 8, 2008. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, (202) 395–5887, or via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to *Judith-B. Herman@fcc.gov,* Federal Communications Commission, or an e-mail to *PRA@fcc.gov*. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review'', (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the

list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0804.

Title: Universal Service—Rural Health Care Program.

Form Nos.: FCC Forms 465, 466, 466–A and 467.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 6,494 respondents; 59,464 responses.

Estimated Time per Response: 10–20 hours.

Frequency of Response: On occasion, monthly, quarterly, annual, and one-time reporting requirements, and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 201–205, 214, 254, and 403.

Total Annual Burden: 67,468 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality. However, respondents may request material or information submitted to the Commission be withheld from public inspection by requesting confidential treatment of their documents under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission submitted this information collection to the OMB as an emergency request and received OMB approved on January 17, 2008. The Commission is now submitting this information collection (IC) to the OMB as an extension (no change in reporting, recordkeeping and/or third party disclosure requirements) during this comment period to obtain the full three-year clearance from them. Due to a mathematical error in the emergency request, the Commission is reporting a −952 hourly adjustment to the total annual burden.

In the Telecommunications Act of 1996 (1996 Act), Congress specifically sought to provide rural health care providers with ''an affordable rate for the services necessary for the provision of telemedicine and instruction relating to such services.'' In 1997, the Commission implemented this statutory directive by adopting the current Rural Health Care support mechanism, which provides universal service support to ensure that rural health care providers pay no more than their urban counterparts for their telecommunications needs and Internet access in the provision of health care services. Despite the Commission's efforts to increase the utility of the Rural Health Care support mechanism, the program has yet to fully achieve the benefits intended by the statute and the Commission.

In particular, health care providers continue to lack access to the broadband facilities needed to support the types of advanced telehealth applications, like telemedicine, that are vital to bringing medical expertise and advantage of modern health technology to rural areas of the nation. In response, the Commission issued the 2007 Pilot Program Selection Order (WC Docket No. 02–60, FCC 07–198) which selected 69 participants for the universal service Rural Health Care Pilot Program (which was originally established by the Commission in September 2006). These 69 participants are eligible for up to 85 percent of the costs associated with: (1) The construction of state or regional broadband health care networks and with the advanced telecommunications and information services provided over those networks; (2) connecting to Internet 2 or National LambdaRail, which are both dedicated nationwide backbones; and (3) connecting to the public Internet. Approximately $417 million in universal service support over three years (or $139 million per funding year) will be available to participants. To minimize the burden on Pilot Program participants and to streamline the process, the Commission generally uses the same forms as the existing Rural Health Care support mechanism. For example, selected participants, in order to receive support, must submit FCC Form 465 (seeking bids), FCC Form 466 (funding request and certification), FCC Form 466–A (selection of service provider), and FCC Form 467 (notification of service initiation). Due to the unique structure of the Pilot Program, however, in the 2007 Pilot Program Selection Order, the Commission provides guidance regarding how these forms should be completed and additional information is required from selected participants, including proposed network costs worksheets, certifications, letters of agency from each participating health care provider, invoices showing actual incurred costs, and if applicable, network design studies.

The information collected provides the Commission with the necessary information to administer the existing program and the Pilot Program, determine the amount of support applicants are eligible to receive, and inform the Commission about the feasibility of revising its rules.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–20743 Filed 9–5–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[MB Docket No. 07–57; FCC 08–178]

Applications for Consent to the Transfer of Control of Licenses, XM Satellite Radio Holdings Inc., Transferor, to Sirius Satellite Radio Inc., Transferee

AGENCY: Federal Communications Commission.

ACTION: Notice; approval of merger.

SUMMARY: This document approves the consolidated application of Sirius Satellite Radio Inc. (''Sirius'') and XM Satellite Radio Holdings Inc. (''XM''; jointly, the ''Applicants'') for consent to the transfer of control of the licenses and authorizations held by Sirius and XM and their subsidiaries for the provision of SDARS in the United States and eliminates the prohibition on one licensee of satellite digital audio radio service (or ''SDARS'') acquiring control of the other SDARS licensee.

DATES: The Commission's action became effective July 25, 2008.

FOR FURTHER INFORMATION CONTACT: Marcia Glauberman, Industry Analysis Division, Media Bureau, at (202) 418–7046, or Rebekah Goodheart, Industry Analysis Division, Media Bureau, at (202) 418–1438.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Memorandum Opinion and Order and Report and Order* (the ''Order'') in MB Docket No. 07–57; FCC 08–178, adopted July 25, 2008, and released August 5, 2008. 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. These documents will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs*). The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. 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 FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Summary of the Order

1. In 1997, the Commission established the SDARS service and determined that there would be two initial SDARS licenses, sold at auction to different parties. The 1997 *SDARS Service Rules Order*, 62 FR 11083, 11102, March 11, 1997 (''1997 Order''), contained the following language:

> Even after DARS licenses are granted, one licensee will not be permitted to acquire control of the other remaining satellite DARS license. This prohibition on transfer of control will help assure sufficient continuing competition in the provision of satellite DARS service.

2. In this Order, the Commission found that the merger would be prohibited by the language in the 1997 Order. For the reasons summarized below, however, the Commission found that approval of the merger, subject to the Applicants' voluntary commitments and other conditions, would benefit consumers by making available to them a wider array of programming choices at various price points and affording them greater choice and control over the programming to which they subscribe, and that those benefits would exceed the harms. For the same reasons, the Commission concluded that elimination of the prohibition on one licensee of SDARS acquiring control of the other SDARS licensee, on balance, would serve the public interest.

3. The Commission's decision was based on consideration of the consolidated application of Sirius and XM for consent to the transfer of control of the licenses and authorizations held by Sirius and XM and their subsidiaries for the provision of SDARS in the United States. After reviewing the empirical data available as part of its competitive analysis, the Commission determined there was insufficient evidence in the record to predict the likelihood of anticompetitive harms. It therefore evaluated the Application under ''worst-case'' assumptions, i.e., that the relevant market is limited to SDARS. This approach permitted the Commission to protect consumers from potential adverse effects of the transaction while also allowing the Commission to balance potential harms against potential public interest benefits. The Commission concluded that the merger, absent the Applicants' voluntary commitments and other conditions, would result in potential harms. The Commission found that, with the Applicants' voluntary commitments and other conditions, the potential public interest benefits of the transaction, on balance, outweigh the potential harms, and approval of the transaction is in the public interest.

4. The Commission conditioned grant of the application on the merged firm's fulfillment of the Applicants' voluntary commitments and other conditions. The Commission accepted the Applicants' voluntary commitments and imposed conditions to:

a. Cap prices for at least 36 months after consummation of the transaction, subject to certain cost pass-throughs after one year. In addition, six months prior to the end of commitment period, the Commission will seek public comment on whether the cap continues to be necessary in the public interest and will determine whether it should be extended, removed, or modified. The merger approval is conditioned on the Commission's ability to modify or extend the price cap beyond the three-year commitment period.

b. Offer to consumers, within three months of consummation of the transaction, the ability to receive a number of new programming packages, including the ability to select programming on an a la carte basis.

c. Make available four percent of its capacity for use by certain Qualified Entities, and an additional four percent of capacity for the delivery of noncommercial educational or informational programming, which will enhance the diversity of programming available to consumers.

d. Offer interoperable receivers in the ''retail after-market,'' i.e., receivers available at retail outlets for installation in consumers' automobiles or homes, within nine months of consummation of the merger.

e. Refrain from entering into any agreement that would grant an equipment manufacturer an exclusive right to manufacture, market, and sell SDARS receivers. Applicants also commit to refrain from barring any manufacturer from including in any receiver non-interfering digital audio broadcast (or, ''HD Radio'') functionality, iPod compatibility, or other audio technology.[1] In addition, Applicants will make available the intellectual property needed to allow any device manufacturer to develop equipment that can deliver SDARS.

f. File the applications needed to provide Sirius satellite service to Puerto Rico via terrestrial repeaters within three months of the consummation of the merger.

5. The Commission reiterated that SDARS licensees are already prohibited, independent of the merger, from using terrestrial repeaters to distribute local content—including both programming and advertising—that is distinct from that provided to subscribers nationwide via satellite. The Commission also prohibited the merged entity from entering into agreements that would bar any terrestrial radio station from broadcasting live local sporting events.

6. The Commission clarified that the merged entity must comply with the Commission's equal employment opportunity rules and policies for broadcasters, including periodic submissions to the Commission consistent with the broadcast reporting schedule.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–20735 Filed 9–5–08; 8:45 am]

BILLING CODE 6712–01–P

[1] Although the Commission found it unnecessary to impose a condition requiring the inclusion of HD Radio technology in SDARS receivers, it recognized that important questions were raised about HD Radio that warrant further examination in a separate proceeding. The Commission will initiate a notice of inquiry within 30 days after adoption of the merger order to gather additional information on the issues.

FEDERAL MARITIME COMMISSION

Meetings; Sunshine Act

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: September 11, 10 a.m.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: A portion of the meeting will be in Open Session and the remainder of the meeting will be in Closed Session.

MATTERS TO BE CONSIDERED:

Open Session

(1) FMC Agreement No. 201192, South Florida Container Terminal Cooperative Working Agreement.

(2) Docket No. 02–04, Anchor Shipping Co. v. Alianca—Request for Extension of Time for Initial and Final Decision.

(3) Constitution Day and Citizenship Day, 2008.

Closed Session

(1) FMC Agreement No. 201170–001, LA Long Beach Port Infrastructure & Environmental Cooperative Working Agreement.

(2) LA/Long Beach Ports/Terminals Agreements.

(3) Export Cargo Issues Status Report.

(4) Internal Administrative Practices and Personnel Matters.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Assistant Secretary, (202) 523–5725.

Karen V. Gregory

Assistant Secretary.

[FR Doc. E8–20899 Filed 9–4–08; 4:15 pm]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 23, 2008.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. The O'Laughlin Group, which consists of Frances L. O'Laughlin, Mesa, Arizona; Terrence L. O'Laughlin, Fayette, Missouri; Jeffrey B. O'Laughlin, Ashland, Missouri; Russell L. O'Laughlin and Kelly D. Wilt, both of Shelbina, Missouri; to acquire control of Community State Bancshares, Inc., and thereby indirectly acquire control of Community State Bank, both of Shelbina, Missouri.

2. Donna Joyce Ramsey, individually and as trustee of the Richard D. Ramsey Revocable Trust, Macon, Missouri, to acquire control of Community State Bancshares, Inc., and thereby indirectly acquire control of Community State Bank, both of Shelbina, Missouri.

Board of Governors of the Federal Reserve System, September 3, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–20718 Filed 9–5–08; 8:45 am]

BILLING CODE 6210–01–S

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 October 3, 2008.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106–2204:

1. SIS Bancorp, MHC and SIS Bancorp, Inc., both of Sanford, Maine, to become a bank holding company by acquiring 100 percent of the voting shares of Sanford Institution for Savings, Sanford, Maine.

B. Federal Reserve Bank of San Francisco (Kenneth Binning, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105–1579:

1. Wells Fargo & Company, San Francisco, California, to acquire 100 percent of the voting shares of Century Bancshares, Inc., Dallas, Texas, and thereby indirectly acquire voting shares of Century Bank, N.A., Texarkana, Texas.

Board of Governors of the Federal Reserve System, September 3, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–20719Filed 9–5–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

TIME AND DATE: 10 a.m. (Eastern Time), September 15, 2008.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC 20005.

STATUS: Parts will be open to the public and parts closed to the public.

MATTERS TO BE CONSIDERED:

Parts Open to the Public

1. Approval of the minutes of the August 18, 2008 Board member meeting.

2. Thrift Savings Plan activity report by the Executive Director.

a. Monthly Participant Activity Report.

b. Monthly Investment Performance Report.

c. Legislative Report.

3. Acquisition of SI International by Serco, Inc.

4. Planning for Potential Emergency Asset Transfer.

5. Annual Budget Report.

a. Fiscal Year 2008 Results.

b. Fiscal Year 2009 Budget.

c. Fiscal Year 2010 Estimate.

Parts Closed to the Public

6. Procurement.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: September 4, 2008.

Thomas K. Emswiler,

Secretary, Federal Retirement Thrift Investment Board.

[FR Doc. E8–20931 Filed 9–4–08; 4:15 pm]

BILLING CODE 6760–01–P

FEDERAL TRADE COMMISSION

Information Collection Activities; Emergency Clearance Submission for Expedited OMB Review; Comment Request

AGENCY: Federal Trade Commission (''Commission'' or ''FTC'').

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (''OMB'') for emergency processing and a request for a temporary, 180-day grant of clearance pursuant to OMB's regulations implementing the Paperwork Reduction Act (''PRA''). The Commission seeks public comments on the PRA burden analysis below for the final amendments to the FTC's Telemarketing Sales Rule (''TSR'' or ''Rule'').

DATES: Comments must be submitted on or before October 8, 2008.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''TSR Final Amendments, PRA Comment, FTC File No. R411001'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Because paper mail in the Washington area and at the FTC is subject to delay, please consider submitting your comments in electronic form, as prescribed below. If, however, the comment contains any material for which confidential treatment is requested, the comment must be filed in paper form, and the first page of the document must be clearly labeled ''Confidential.''[1]

Comments filed in electronic form should be submitted by following the instructions on the web-based form at: (*https://secure.commentworks.com/ftc-TSRpra*). To ensure that the Commission considers an electronic comment, you must file it on the web-based form at (*https://secure.commentworks.com/ftc-TSRpra*). You may also visit *http://www.regulations.gov* to read this notice, and may file an electronic comment through that website. The Commission will consider all comments that *www.regulations.gov* forwards to it.

All comments should additionally be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395-6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC website, to the extent practicable, at *www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements for the Franchise Rule should be addressed to Craig Tregillus, Staff Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Room H-238, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580, (202) 326-2970.

SUPPLEMENTARY INFORMATION:

The current OMB approval—or ''clearance''— for the information collection requirements in the TSR[2] expires on July 31, 2009. The OMB clearance, issued in 2006, does not encompass the new information collection requirements of the recent amendments to the TSR.[3] The Commission now seeks OMB review and approval and public comment regarding the PRA impact of those amendments.

The Commission is requesting expedited OMB review and emergency clearance because the use of normal clearance procedures under 5 CFR 1320.12 will likely disrupt the collection of information for the earlier of two PRA-related amendments to the TSR, for which compliance will be enforced beginning December 1, 2008. A grant of 180 days clearance will provide the FTC added time to: (a) publish for public comment a **Federal Register** notice stating FTC staff estimates of incremental PRA burden associated with the final Rule amendments; (b) pursue thereafter under 5 CFR 1320.12 normal clearance procedures for the revised Rule as a whole; (c) review of any public comments received for these respective notices; (d) prepare related supporting statements for OMB's review. The Commission requests OMB approval by October 31, 2008.

As previously proposed, the TSR amendments concerning prerecorded calls and calculation of call abandonment rates did not affect PRA burden.[4] Accordingly, with no changes to staff's prior estimates of PRA burden at that time, no OMB review and approval for the proposed amendments was sought.

The final amendments, however, contain requirements that arguably constitute a ''collection of information'' under the PRA.[5] Specifically, the final prerecorded call amendment expressly authorizes sellers and telemarketers to place outbound prerecorded telemarketing calls to consumers if: (1) the seller has obtained written agreements from those consumers to receive prerecorded telemarketing calls after a clear and conspicuous disclosure of the purpose of the agreement; and (2) the call discloses an opt-out mechanism at the outset of the call.[6] The amendment will apply not only to prerecorded calls that are answered by a consumer, but also to prerecorded messages left on consumers' answering machines or voicemail services.

Staff continues to believe, however, that the amendment for calculating the call abandonment rate, which remains unchanged from the proposed rulemaking, will not affect the Rule's PRA burden. The amendment relaxes the present requirement that the abandonment rate be calculated on a ''per day per campaign'' basis by

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] OMB Control Number 3084-0097.

[3] 73 FR 51164 (August 29, 2008).

[4] 71 FR 58716, 58730-58731 (Oct. 4, 2006).

[5] Under the PRA, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c).

[6] When it takes effect, the prerecorded call amendment will provide the first ever explicit authorization in the TSR for sellers and telemarketers to place prerecorded telemarketing calls to consumers. The call abandonment prohibition of the TSR now implicitly prohibits such calls by requiring that all telemarketing calls be connected to a sales representative, rather than a recording, within two seconds of the completed greeting of the person who answers. 16 CFR 310.4(b)(1)(iv).

permitting, but not requiring, its calculation over a 30-day period as requested by the industry. Sellers and telemarketers already have established automated recordkeeping systems to document their compliance with the current standard. The amendment likely will reduce their overall compliance burden because it relaxes the current requirement. The current ''per day'' requirement has forced telemarketers to turn off their predictive dialers on many occasions when unexpected spikes in call abandonment rates occur late in the day, and thereby has prevented realization of the cost savings that predictive dialers provide.

The prerecorded call amendment will take effect in two stages. A requirement that prerecorded calls provide an automated interactive keypress or voice-activated opt-out mechanism will take effect December 1, 2008, but the prohibition on placing calls that deliver prerecorded messages without the prior express written agreement of the recipient to receive such calls will not take effect until September 1, 2009.

The written agreement requirement of the prerecorded call amendment will substitute the means of compliance under the Commission's forbearance policy[7] and the recordkeeping requirements of the TSR—which now require a record of an established business relationship (''EBR'')[8]—with a record of a consumer's agreement to receive prerecorded calls.[9] This substitution should not materially change the TSR's recordkeeping burden. While there will be some initial burden in converting from EBR records to agreement records, the Commission has taken two additional steps designed to reduce that burden significantly. First, the Commission will accept agreements obtained pursuant to the Electronic Signatures In Global and National Commerce Act, Pub. L. No. 106-229, 114 Stat. 464 (2000) (codified at 15 U.S.C. 7001 et seq.) (''E-SIGN Act''), including the use by consumers of a keypress on a telephone keypad. Second, the Commission has provided a phase-in that defers the written agreement requirement until September 1, 2009, during which time sellers may continue to place low-cost prerecorded calls to their EBR customers that could include a request for agreement to receive prerecorded calls in the future with a simple keypress.

The FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Estimated incremental annual hours burden: 82,865 hours

When the FTC last sought renewed PRA clearance for the Rule, staff estimates were based on data from the FTC's Do-Not-Call Registry (''Registry''). The most recent full-year data then available was for the period from 3/1/05 - 2/28/06. In order to focus strictly on the incremental PRA burdens posed by the final Rule amendments, we use data for the same time period in this burden analysis.[10] To obtain figures for sellers only, however (because only they, not telemarketers, will have new compliance obligations attributable to the final amendments), we have analyzed the 2006 data in greater detail.

In seeking the 2006 clearance, staff estimated that 15,000 telemarketing entities (sellers and the telemarketers that serve them) were subject to the Rule.[11] New Registry data for the period 3/1/05 - 2/28/06 that we believe is more accurate shows that the total number of telemarketing entities subject to the TSR is 19,208.[12] Of that total, there were 4,393 sellers and also 2,635 telemarketers with independent access to the Registry that downloaded telephone numbers from more than one state (to avoid TSR violations by automated ''scrubbing'' of the numbers on the Registry from their calling lists).[13] The number of *sellers* subject to the TSR, therefore, is 16,573 (19,208 telemarketing entities - 2,635 telemarketers =16,573 sellers).

Recordkeeping: Under the amendment, no prerecorded call may be placed by or on behalf of a seller unless the seller has obtained a written agreement from the person called to receive such calls. Thus, the recordkeeping obligations of the prerecorded call amendment fall on sellers rather than telemarketers.[14]

In view of the phase-in and the amendment's clarification allowing written agreements to be created and maintained electronically pursuant to the E-SIGN Act, any initial burden caused by the transition from EBR records to written agreement records should not be material. Once the necessary systems and procedures are in place, any ongoing incremental burden to create and retain electronic records of agreements by new customers to receive prerecorded calls should be minimal.[15]

Staff estimates that each of the 16,573 sellers subject to the prerecorded call amendment will require approximately 1 hour to prepare and maintain records required by the amendment; thus, 16,573 total recordkeeping hours. This reflects a one-time modification of existing customer databases to include an additional field to record consumer agreements.

Disclosure: Staff estimates that the 16,573 sellers will require, on average, 4 hours each—66,292 hours cumulatively—to implement the incremental disclosure requirements posed by the final rule amendments.

[7] 69 FR 67287, 67288-62790 (Nov. 17, 2004). The enforcement forbearance policy has permitted such calls if they provide either: (1) a telephone keypad mechanism a consumer can use to opt-out of future calls from the seller, or (2) a toll-free telephone number a consumer can call to opt-out. In October 2006, when the Commission proposed to require a prior written agreement for prerecorded calls, it also proposed to terminate the forbearance policy as of January 4, 2007, but was persuaded by several industry petitions to preserve the status quo until the conclusion of the amendment proceeding.

[8] 16 CFR 310.2(n) (defining an EBR); 16 CFR 310.5(a)(3) (EBR recordkeeping requirement).

[9] 16 CFR 310.5(a)(5) (written agreement recordkeeping requirement).

[10] We will update our population estimates in early 2009 when preparing our next PRA clearance request for the amended TSR as a whole.

[11] *See* 71 FR 28698 (May 17, 2006) and the associated May 2006 supporting statement submitted to OMB for the details underlying this estimate.

[12] This figure, derived from data provided from the Registry's current contractor, is determined as follows: 65,768 total entities accessing the Registry - 933 exempt entities - 45,627 non-exempt entities that accessed telephone numbers solely intrastate (and thus not subject to the TSR) = 19,208. (This calculation employs the same methodology as was used in the 2006 clearance request.)

[13] Staff assumes that telemarketers that make prerecorded calls download telephone numbers listed on the Registry rather than conduct online searches as the latter may consume considerably more time. Other telemarketers not placing the high-volume of automated prerecorded calls may elect to search online, rather than to download.

[14] Although telemarketers that place prerecorded telemarketing calls on behalf of sellers must capture and transmit to the seller any requests they receive to place a consumer's telephone number on the seller's entity-specific do-not-call list, this *de minimis* obligation extends both to live and prerecorded telemarketing calls, and was accounted for in the 2006 estimates. Moreover, software that automates this process for prerecorded calls is widely available and in use.

[15] If it is not feasible to obtain a written agreement at the point of sale after the written agreement requirement takes effect, sellers could, for example, obtain a customer's email address and request an agreement via email to receive prerecorded calls.

This estimate is comprised of the following tasks: (1) one-time creation, recording, and implementation of a brief telephone script requesting a consumer's agreement via a telephone keypad response;[16] (2) modify or create electronic forms or agreements for use in emails to consumers or on a website;[17] (3) one-time revision of any existing paper forms (*e.g.*, credit card or loyalty club forms, or printed consumer contracts) to include a request for the consumer's agreement to receive prerecorded calls;[18] and (4) legal consultation, if needed, regarding compliance.

Any remaining time needed to make the required opt-out disclosure for all prerecorded calls would pose no greater time increment, and arguably less, than a similar, pre-existing Federal Communications Commission disclosure provision that has been in effect since 1993.[19] In any event, because this disclosure applies only to prerecorded calls, which are fully automated, no additional manpower hours would be expended in its delivery.

Other: The revised standard for measuring the three percent call abandonment rate will not impose any new or affect any existing reporting, recordkeeping or third-party disclosure requirements within the meaning of the PRA. The amendment relaxes the present requirement that the abandonment rate be calculated on a ''per day per campaign'' basis by permitting, but not requiring, its calculation over a 30-day period as requested by the industry. Sellers and telemarketers already have established automated recordkeeping systems to document their compliance with the current standard. The proposed amendment likely will reduce their overall compliance burden because it relaxes the current requirement. The current ''per day'' requirement has forced telemarketers to turn off their predictive dialers on many occasions when unexpected spikes in call abandonment rates occur late in the day, and thereby prevented realization of the cost savings that predictive dialers provide.

Estimated incremental labor cost burden: $3,488,000, rounded

Recordkeeping: As indicated above, staff estimates that existing sellers making use of prerecorded calls will require 16,753 hours, cumulatively, to comply with the amendment's recordkeeping requirements during the final year of the current PRA clearance. Staff assumes that the aforementioned tasks will be performed by managerial and/or professional technical personnel, at an hourly rate of $38.93.[20] Accordingly, incremental labor cost in the final year of the current clearance would be $652,194.

Disclosure: Staff estimates that approximately 75% of the disclosure-related tasks previously noted would be performed by managerial and/or professional technical personnel, again, at an hourly rate of $38.93, with 25% allocable to legal staff, at an hourly rate of $54.35.[21]

Thus, of the 66,292 total estimated disclosure burden hours, 49,719 hours would be attributable to managerial and/or professional technical personnel, with the remaining 16,573 hours attributable to legal staff. This yields $1,935,561 and $900,743, respectively, in labor cost—in total, $2,836,304.

Cumulatively, for recordkeeping and disclosure, labor cost would total $3,488,498 for the final year of the current clearance.

Other than the initial recordkeeping costs, the amendment's written agreement requirement will impose *de minimis* costs, as discussed above. The one possible exception that might arise involves credit card or loyalty program agreements that retailers revise to request agreements from consumers to receive prerecorded calls. Retailers might have to replace any existing supplies of such agreements. Staff believes, however, that the one-year phase-in of the written agreement requirement will allow retailers to exhaust existing supplies of any such preprinted forms, so that no material additional cost would be incurred to print revised forms.

Similarly, staff has no reason to believe that the amendment's requirement of an automated interactive opt-out mechanism will impose other than *de minimis* costs, for the reasons discussed above. The industry comments on the amendment uniformly support the view that automated interactive keypress technologies are now affordable, cost-effective, and widely available.[22] Moreover, most, if not all of the industry telemarketers who commented, including many small business telemarketers, said they are currently using interactive keypress mechanisms. Thus, it does not appear that this requirement will impose any material capital or other non-labor costs on telemarketers.

David C. Shonka

Acting General Counsel

[FR Doc. E8–20775 Filed 9–8–08; 8:45 am]

BILLING CODE 6750–01–S

[16] During the one-year phase-in before the written agreement requirement takes effect, the Commission will permit sellers to use prerecorded message calls made to existing customers to secure their agreements to receive prerecorded calls by pressing a key on their telephone keypad. Once a script is written and recorded, it can be used in all calls made by or on behalf of the seller to obtain the required agreements. Sellers will be able to include the request for the agreement in their regular prerecorded calls, thus making the time necessary to request the required agreements, and the cost of doing so, *de minimis* during the year-long phase-in that will overlap with the final year of the current PRA clearance.

[17] This figure includes both the minimal time required to create the electronic form and the time to encode it in HTML for the seller's website.

[18] As previously noted, the Commission has provided suggested language for this purpose that should minimize the time required to modify any paper disclosures.

[19] 47 CFR 64.1200(b)(2) (requiring disclosure of a telephone number ''[d]uring or after the message'' that consumers who receive a prerecorded message call can use to assert a company-specific do-not-call request).

[20] This cost is derived from the median hourly wage from the 2006 National Occupational Employment and Wage Estimates by the Bureau of Labor Statistics for management occupations. *See* (*http://www.bls.gov/oes/current/oes_nat.htm#b11-0000*).

[21] This cost is derived from the median hourly wage for lawyers from the ''National Compensation Survey: Occupational Wages in the United States, June 2006,'' Table 2. *See* (*http://www.stats.bls.gov/ncs/ocs/sp/ncbl0910.pdf*).

[22] *See, e.g.*, Comment by IAC/InterActiveCorp & HSN LLC (December 18,2006), at 3, *available at* (*http://www.ftc.gov/os/comments/tsrrevisedcallabandon/525547-00600.pdf.*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Meeting

ACTION: Meeting Announcement.

SUMMARY: This notice announces the meeting date for the 24th meeting of the American Health Information Community in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.) The American Health Information Community will advise the Secretary and recommend specific actions to achieve a common interoperability framework for health information technology (IT).

Meeting Date: September 23, 2008, from 8:30 a.m. to 3 p.m. (Eastern).

ADDRESSES: Hubert H. Humphrey building (200 Independence Avenue, SW., Washington, DC 20201), The Great Hall/Lobby.

SUPPLEMENTARY INFORMATION: The meeting will include a demonstration of the Nationwide Health Information Network (NHIN); an update on the AHIC

Successor organization; a discussion on the health information technology Strategic Plan; and final reports from the Confidentiality, Privacy & Security Workgroup and the Population Health/ Clinical Care Connections Workgroup.

FOR FURTHER INFORMATION: Visit *http://www.hhs.gov/healthit/ahic.html.*

A Web cast of the Community meeting will be available on the NIH Web site at: *http://www.videocast.nih.gov/.*

If you have special needs for the meeting, please contact (202) 690–7151.

Dated: August 26, 2008.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. E8–20675 Filed 9–5–08; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

FDA Clinical Trial Requirements Regulations, Compliance, and Good Clinical Practice Conference; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates(SoCRA), is announcing a workshop on FDA Clinical Trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, November 19, 2008, from 8 a.m. to 5 p.m. and Thursday, November 20, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Westin Crown Center, 1 East Pershing Rd., Kansas City, MO 64118, 816–474–4400, FAX: 816–391–4438.

Contact: David Arvelo, Food and Drug Administration, 4040 N. Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *david.arvelo@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), $525 (government employee nonmember), or $450 (government employee member). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914. To register via the Internet go to *http://www.socra.org/html/FDA_Conference.htm* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Westin Crown Center at the reduced conference rate, contact the Westin Crown Center (see Location) before October 21, 2008. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited; therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact*) at least 21 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conference, helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA and confidence in the conduct of clinical research; (2) medical device, drug, biological product, and food additive aspects of clinical research; (3) investigator initiated research; (4) Pre-investigational new drug (IND) application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of Institutional Review Boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections, and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: September 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20730 Filed 9–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the National Diabetes Education Program Comprehensive Evaluation Plan

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 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The National Diabetes Education Program Comprehensive Evaluation Plan. *Type of Information Collection Request:* Extension of a currently approved collection (#0925–0552). *Need and Use of Information Collection:* The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to: Improve the treatment and health outcomes of people with diabetes, promote early diagnosis, and, ultimately, prevent the onset of diabetes. The NDEP objectives are: (1)

To increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among people at risk for diabetes; (2) to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes; (3) to improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care; (4) to promote health care policies that improve the quality of and access to diabetes care.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) Creating partnerships with other organizations concerned about diabetes; (2) developing and implementing awareness and education activities with special emphasis on reaching the racial and ethnic populations disproportionately affected by diabetes; (3) identifying, developing, and disseminating educational tools and resources for the program's diverse audiences; (4) promoting policies and activities to improve the quality of and access to diabetes care.

The NDEP evaluation will document the extent to which the NDEP program has been implemented, and how successful it has been in meeting program objectives. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This generic clearance request is for the collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. Approval is requested for a survey of audiences targeted by the National Diabetes Education Program including people at risk for diabetes, people with diabetes and their families and the public.

Frequency of Response: On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3759, *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .153; and *Estimated Total Annual Burden Hours Requested:* 575. There are no Capital, Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Total hour burden
Screening interview with ineligible persons	1659	1	.03	50
Eligible respondents	2100	1	.25	525
Totals	3759			575

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 Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, NIDDK, NIH, Building 31, Room 9A06, 31 Center Drive, Bethesda, MD 20892, call the non-toll-free number 301–494–6110 or e-mail your request, including your address to: *Joanne_Gallivan@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: June 9, 2008.

Elizabeth E. Greene,

Executive Officer, NIDDK, National Institutes of Health.

Editorial Note: This document was received in the Office of the Federal Register on September 3, 2008.

[FR Doc. E8–20636 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Simulations for Drug Related Science Education

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 26, 2008, (Vol. 73 No. 124, page 36337) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after September 24, 2008, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Simulations for Drug Related Science Education. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for a one-time clearance to evaluate an interactive multimedia module developed by *ArchieMD.* This evaluation seeks to determine whether the multimedia module *Archie MD: The Science of Drugs* (1) Increases students' knowledge in brain and heart biology and the effects drugs have on the body (2) Increases positive attitudes towards science education for high school students (3) Reinforce or instill negative

attitudes towards substance abuse. In order to test the effectiveness of the interactive multimedia module, data will be collected in the form of pre and post test surveys from 10th and 11th grade high school students utilizing the developed module. The findings will provide valuable information regarding information pertaining to the use of interactive multimedia educational modules in high school science classrooms and their ability to increase knowledge and change attitudes and perceptions.

Frequency of Response: 4. *Affected Public:* High school students engaged with the *ArchieMD: The Science of Drugs* program. *Type of Respondent:* Participants will include high school students enrolled in the tenth and eleventh grade. *Estimated Total Annual Number of Respondents:* 360. *Estimated Number of Responses per Respondent:* 4. *Average Burden Hours per Response:* One high school period lasting 50 minutes. *Estimated Total Annual Burden Hours Requested:* 1199.95. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The estimated annualized burden is summarized below.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Estimated total burden hours requested
Participants—High School Students	360	4	.8333	1199.95
Total	360	4	.8333	1199.95

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 functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plans, please contact Dr. Cathrine Sasek, Coordinator, Science Education Program, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Blvd, Room 5237, Bethesda, MD 20892, or call non-toll-free number (301) 443–6071; fax (301) 443–6277; or by e-mail to *csasek@nida.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: August 25, 2008.

Mary Affeldt,

Associate Director for Management, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. E8–20778 Filed 9–5–08; 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.

Over-Expression and Mutation of a Tyrosine Kinase Receptor FGFR4 in Tumors

Description of Technology: Rhabdomyosarcoma (RMS) is the most common type of pediatric soft tissue sarcoma. Most children (>70%) with the disease die at higher stage (metastatic disease).

Researchers at NIH have identified mutations in fibroblast growth factor receptor 4 (FGFR4) that are associated with RMS tumors. It is proposed that individuals with FGFR4 mutations may have an increased risk for tumor metastasis. The identified FGFR4 variants can be used to identify individuals who may benefit most from treatment with an FGFR4 inhibitor as an adjuvant to standard anticancer therapeutics to decrease the risk of tumor metastasis.

Available for licensing are methods for identifying candidates for treatment with an inhibitor of FGFR4 by determining the presence of at least one FGFR4 variant, kits for identifying said candidates, and methods for identifying compounds that induce tumor cell death or that inhibit tumor growth or metastasis.

Applications:

- Potential new method for treatment of Rhabdomyosarcomas (RMS).
- Potential new method to prepare kits to diagnose activating mutations in FGFR4.
- These mutations can be used in laboratory settings to screen thousands of compounds for more specific FGFR4 gene inhibitors.
- FGFR4 is also a potential target for lung and breast cancer.
- FGFR4 monoclonal can be developed to target RMS tumors.

Market:

- In the United States, approximately 12,000 new cases of cancer are diagnosed in children each year. Childhood cancer remains the leading disease-related cause of death in children and adolescents in North America, with about 2,300 deaths each year.
- Rhabdomyosarcoma accounts for about 3 percent of childhood cancers. In the U.S., about 350 children are diagnosed with Rhabdomyosarcoma each year.

Development Status: Early-stage of development.

Inventors: Javed Khan *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/044,875 filed 14 Apr 2008 (HHS Reference No. E–175–2008/0–US–01).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Pediatric Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Over-expression and Mutation of a Tyrosine Kinase Receptor FGFR4 in Tumors. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Small Molecule Inhibitors of c-Met

Description of Technology: Aberrant c Met signaling is documented in a wide variety of malignancies and occurs via several mechanisms including amplification of c-Met (increased gene copy number), point mutations in the gene encoding c-Met, receptor over-expression, and ligand dependent autocrine/paracrine receptor activation. This application describes novel small molecule inhibitors of c-Met signaling. The small molecules selectively bind to c-Met and have an IC50 in the micromolar range. The small molecules belong to two different families. One family of small molecules reduces the level of c Met expression via receptor down-regulation and blocks ATP binding. The other family of small molecules block ATP binding without inducing receptor down-regulation. Evidence suggests that the second family of compounds bind to both active and inactive conformations of c-Met.

Applications: Therapy for cancers associated with aberrant c-Met signaling, for example bladder, breast, cervical, colorectal, endometrial, esophageal, gastric, head and neck, kidney, liver, lung, nasopharyngeal, ovarian, pancreatic, prostate and thyroid cancers, as well as cholangiocarconoma, osteosarcoma, rhabdomyosarcoma, synovial sarcoma, Kaposi's sarcoma, leiomyosarcomas and MFH/fibrosarcoma. In addition to these malignancies, aberrant c Met signaling is associated with hematological malignancies such as acute myelogenous leukemia, adult T cell leukemia, chronic myeloid leukemia, lymphomas and multiple myeloma as well as other tumors like melanoma, mesothelioma, Wilms' tumor, glioblastomata and astrocytomas.

Market: Although the percentage of cancers associated with aberrant c Met signaling is not yet well established, the wide variety of cancers associated with aberrant c Met signaling are indicative of a potentially large market for these compounds. For example, worldwide over 1 million persons per year are diagnosed with colorectal cancer and it is the most common gastrointestinal cancer in industrialized countries. In one study of colorectal cancer 69% of the patients had at least a two-fold elevation of cMet mRNA and 48% of the patients had at least a ten fold elevation of c Met mRNA. In a study of breast cancer, 22% of patients with invasive ductal breast tumor specimens exhibited strong expression of c Met and patients exhibiting c Met expression had only a 52% 5 year survival rate compared with an 89% 5 year survival rate in patients with normal c Met levels.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Donald P. Bottaro, Terrence Burke, Jr., *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/041,523 filed 01 Apr 2008 (HHS Reference No. E–332–2007/0–US–01).

Publications: The patent application has not been published. There are no journal articles available related to this work.

Licensing Status: Available for licensing on an exclusive or non-exclusive basis.

Licensing Contact: Susan S. Rucker; 301–435–4478; *Susan.Rucker@nih.hhs.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize small molecule inhibitors of the HGF/c-Met signaling pathway. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Quantitative Immunoassays for Measurement of Topoisomerase I as a Pharmacodynamic Marker for the Effect of Anti-Cancer Drugs

Description of Technology: Topoisomerase I (TopoI) is an enzyme that catalyses DNA unwinding which is necessary for many cellular functions. Recent data from the Fluorouracil, Oxaliplatin, CPT–11: Use and Sequencing (FOCUS) trial demonstrates that nuclear staining of TopoI correlates with chemotherapy efficacy [J Clin Oncol (2008) 26, 2690–8]. This enzyme covalently binds with the DNA substrate and introduces a single strand break. Some anti-cancer drugs, including those in clinical trials target this cleavage site and prevent re-ligation of the unwound DNA, trapping the TopoI/DNA covalent complex. TopoI trapped by Topo I inhibitor compounds such as Topotecan is degraded by the ubiquitin/proteosome pathway. This change in intracellular TopoI levels makes total TopoI and the TopoI/DNA covalent complex potential pharmacodynamic biomarkers for monitoring TopoI inhibiting agents, used in cancer therapy.

The technology involves a validated, enzyme linked immunosorbent assay (ELISA) with a chemiluminescence readout, using commercially available antibodies to quantitate total TopoI from cell and tumor extracts.

This technology has been used in a high throughput assay for measurement of estrogen and estrogen metabolites in serum. A similar ELISA assay has also been used in NCI Phase 0 and Phase I clinical trials of a PARP inhibitor

Applications:

- Anti-cancer drug testing.
- Patient selection for anti-cancer drug treatment.

Advantages:

- Simple, quantitative, sensitive (LLQ ~40pg/well LLOD= (LOD 220 pg/ml as formulated), range 200 pg/ml to 50ng/ml).
- Uses commercially available antibodies.
- Excludes the use of radioisotopes.
- Validated Assay.
- SOP available.
- In vitro data support use in anti-cancer drug treated melanoma cell lines.
- Mouse model data support use in anti-cancer drug treated melanoma and colon cancer xenografts.

Developmental Status: ELISA was developed in support of Phase I clinical trial on experimental TopoI inhibiting drugs.

Publication: Thomas D. Pfister, Ralph E. Parchment, Joseph Tomaszewski, James Doroshow and Robert J. Kinders. ''Development of a quantitative immunoassay for measurement of topoisomerase I covalent complex as a pharmacodynamic marker for the effect of anti-cancer drugs.'' AACR Annual Meeting, Los Angeles, CA April 14–18, 2007.

Inventors: Thomas D. Pfister and Robert J. Kinders (SAIC/NCI).

Patent Status: HHS Reference No. E–100–2007/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing of biological material.

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute's Laboratory of Human Toxicology and Pharmacology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Quantitative Immunoassays for Measurement of Topoisomerase I as a Pharmacodynamic Marker for the Effect of Anti-Cancer Drugs. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

New Tumor Endothelial Markers: Genes That Distinguish Physiological and Pathological Angiogenesis

Description of Technology: Angiogenesis, the formation of new blood vessels, is associated with normal physiological processes such as wound healing, ovulation or menstruation as well as with many diseases. Presently, it is thought to be required for the progressive growth of solid tumors and age-related macular degeneration. Lack of disease-specific endothelial markers has hindered the development of cancer therapies targeted against angiogenesis.

This invention describes specific markers that can be used to identify tumor angiogenesis, separate from normal physiological angiogenesis. Several markers have been identified which may serve as potential targets for tumor vessels by using comparative gene expression analysis on various normal and tumor endothelial cells. Furthermore, the invention describes several organ-specific endothelial markers that can aid in the selective delivery of molecular medicine to specific sites. For example, brain endothelial markers (BEMs) and liver endothelial markers (LEMs) described herein could potentially be used to direct molecular medicine specifically to these tissues.

The novel tumor endothelial markers (TEMs) described in this invention also have potential diagnostic ability. These markers can be used to distinguish between normal and tumor tissues. Some of the secreted TEMs can serve as surrogate markers in the determination of the optimum biological dose (OBD) for the current anti-angiogenic drugs in clinical trials.

Applications and Modality:

- Novel therapeutic targets associated with tumor vessels.
- New agents can be developed against these novel targets.
- Novel endothelial markers that distinguish pathological angiogenesis from normal physiological angiogenesis.
- Surrogate tumor endothelial markers that can be used to determine optimal biological dose (OBD) of anti-angiogenic drugs.

Market:

- Sales of the first FDA approved anti-angiogenic drug Avastin™ has reached $600 million.
- Another promising anti-angiogenic molecule, Thalidomide™, has been approved as an anti-cancer agent and for other use in Europe and Australia.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Brad St. Croix and Steven Seaman (NCI).

Relevant Publication: A Nanda and B St. Croix. Tumor endothelial markers: new targets for cancer therapy. Curr Opin Oncol. 2004 Jan;16(1):44–49.

Patent Status:

- U.S. Provisional Application No. 60/858,068 filed 09 Nov 2006 (HHS Reference No. E–285–2006/0–US–01).
- U.S. Provisional Application No. 60/879,457 filed 08 Jan 2007 (HHS Reference No. E–285–2006/1–US–01).
- PCT Application No. PCT/US2007/072395 filed 28 Jun 2007, which published as WO 2008/057632 on 15 May 2008 (HHS Reference No. E–285–2006/2–PCT–01).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Collaborative Research Opportunity: The NIH National Cancer Institute, Tumor Angiogenesis Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize specific biomarkers that can be used to identify tumor angiogenesis. Please contact John D. Hewes, PhD at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

Methods of Treating and Preventing Renal Cancer Using a Dimethane Sulfonate Compound

Description of Technology: Currently only a few small molecule inhibitors are effective in patients with renal cell carcinoma. Approximately 30,000 patients per year are diagnosed with this disease but many of them are untreatable because of intrinsic drug resistance, and efficient drug transport and detoxification mechanisms. This invention described and claimed in the patent application describes a series of dimethane sulfonate compounds based on NSC 281612 that are suitable for the treatment of renal cancer. Compositions comprising a pharmaceutically-acceptable carrier and a compound, or a salt suitable for use in the treatment or prevention of renal cancer are also described. The anti-tumor activity of NSC 281612 has been established in vivo against human renal tumor xenografts in mice. Suitable dosing and administration schedules for treatment of renal tumors have also been determined in this study.

Applications: For treatment or prevention of renal cancer.

Development Status: The technology is currently in the pre-clinical stage of development. Phase I clinical trials will begin this fall.

Inventors: Susan D. Mertins, Susan E. Bates, David G. Covell, Geoffrey W. Patton, Melinda G. Hollingshead, B. Rao Vishnuvajjala (NCI).

Patent Status: U.S. Patent Application No. 12/083,583 filed 14 Apr 2008, claiming priority to 14 Oct 2005 (HHS Reference No. E–249–2005/0–US–04).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Screening Technologies Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize biomarker assays for clinical utility (potential molecular targets have been identified). Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

2-Amino-O^4-Substituted Pteridines: Improved Chemotherapy Adjuvants

Description of Technology: O^6-Benzylguanine derivatives, some O^6-benzylpyrimidines, and related compounds are known to be inactivators of the human DNA repair protein O^6-alkylguanine-DNA alkyltransferase (alkyltransferase). This repair protein is the primary source of resistance many tumor cells develop when exposed to chemotherapeutic agents that modify the O^6-position of DNA guanine residues. Therefore, inactivation of this protein can bring about a significant improvement in the therapeutic effectiveness of these chemotherapy drugs. The prototype inactivator O^6-benzylguanine is currently in clinical trials in the United States as an adjuvant in combination with the chloroethylating agent 1, 3-bis (2-chloroethyl)-1-nitrosourea (BCNU) and the methylating agent temozolomide. A

similar alkyltransferase inactivator, O^6-(4-bromothenyl) guanine is in clinical trials in the UK.

This technology is directed to the discovery of a new class of potent alkyltransferase inactivators, 2-amino-O^4-benzylpteridine derivatives targeted for use in cancer treatment in combination with chemotherapeutic agents such as 1, 3-bis (2-chloroethyl)-1-nitrosurea (BCNU) or temozolomide. The derivatives of the present invention inactivate the O^6-alkylguanine-DNA-alkyltransferase repair protein and thus enhance activity of such chemotherapeutic agents. Some of the derivatives are water soluble and possess tumor cell selectivity in particular by inactivating alkyltransferase in tumor cells that overexpress folic acid receptors. The 2-amino-O^4-benzylpteridine derivatives represent a promising new class of alkyltransferase inactivator with representatives that may be great candidates as chemotherapy adjuvants.

Applications and Modality:

- New small molecules as alkyltransferase inactivators based on 2-amino-O^4-benzylpteridine compounds.
- Promising candidates as chemotherapy adjuvants for the treatment of cancer.
- Therapeutic application for drug resistant tumors where acquired resistance is caused by O^6-alkylguanine-DNA alkyltransferase.

Market:

- 600,000 deaths from cancer related diseases estimated in 2006.
- This technology involving small molecule therapeutics for the treatment of several cancers has a potential market of several billion U.S. dollars.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Robert C. Moschel (NCI) *et al.*

Publication: ME Nelson, NA Loktionova, AE Pegg, RC Moschel. 2-amino-O^4-benzylpteridine derivatives: Potent inactivators of O^6-alkylguanine-DNA alkyltransferase. J Med Chem. 2004 Jul 15;47(15):3887–3891.

Patent Status:

- U.S. Patent Application No. 10/585,566 filed 29 Aug 2006, claiming priority to 06 Jan 2004 (HHS Reference No. E–274–2003/0–US–03).
- Foreign equivalents

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Dated: August 26, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–20651 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel EARDA.

Date: October 3, 2008.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 4B01 CRMC, Rockville, MD 20852.

Contact Person: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver National Institute for Child Health & Development, 1600 Executive Boulevard, 5B01, Bethesda, MD 20812–7510, (301) 435–8382, *hindialm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–20644 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; The Role of Human Milk in Infant Nutrition and Health.

Date: October 7, 2008.

Time: 2 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rita Anand, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd, Room 5B01, Bethesda, MD 20892, (301) 496–1487, *anandr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–20646 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; National Children's Study Repository, RFP: NIH–NICHD–NCS–09–07.

Date: October 6, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PHD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–20647 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Communication Disorders Review Committee.

Date: October 15–16, 2008.

Time: October 15, 2008, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Time: October 16, 2008, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Shiguang Yang, DVM, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NIDCD, NIH, 6120 Executive Blvd., Suite 400C, Bethesda, MD 20892, 301–435–1425, *yangshi@nidcd.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 29, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–20681 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Live, Attenuated Virus Vaccines Against RSV, PIV, and hMPV

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of worldwide exclusive license to practice the invention embodied in:

RSV Technologies

(1) U.S. Patents 5,993,824 (issued November 30, 1999) and associated pending U.S. patent applications, serial numbers 10/934,003 (filed September 2, 2004) and 10/722,000 (filed November 25, 2003) and associated foreign rights from PCT applications PCT/US97/12269 (filed July 15, 1997) and PCT/US00/08802 (filed March 31, 2000) (HHS references E–142–1996/0,3,4);

(2) U.S. Patent 6,713,066 (issued March 30, 2004) and associated pending U.S. patent application, serial number 11/011,502 (filed December 13, 2004) and associated foreign rights from PCT application PCT/US00/18534 (HHS reference E–194–1999/0);

(3) PCT application PCT/US00/09695 and associated foreign rights therefrom (HHS reference E–040–1999/0);

(4) U.S. patent applications, serial numbers 11/054,343 (filed February 9, 2001) and 11/033,055 (filed January 10, 2005), and associated foreign rights from PCT application PCT/US01/20107 (HHS reference E–225–2000/0).

PIV Technologies

(1) U.S. Patents 6,410,023 (issued June 25, 2002); 7,208,161 (issued April 24, 2007); 7,314,631 (issued January 1, 2008); 7,250,171 (issued July 31, 2007); and pending U.S. patent application, serial number 11/785,364 (filed April 17, 2007), and associated foreign rights through PCT applications PCT/US98/10551 (filed May 22, 1998) and PCT/US00/18523 (filed July 6, 2000) (filed December 8, 2000) (HHS references E–089–1997/2,3,4,5,6,7);

(2) U.S. patent application, serial number 10/667,141 (filed September 18, 2003) and associate foreign rights from PCT/US03/29685 (filed September 18, 2003) (HHS reference E–092–2002/0);

(3) U.S. patent application (serial number pending, filed January 10, 2006) and associated foreign rights from PCT/US2006/000666 (filed January 10, 2006) (HHS reference E–295–2004/0);

(4) U.S. patent application, serial number 10/302,547 (filed November 21, 2002) and associated foreign rights from PCT/US02/37688 (filed November 21, 2002) (HHS reference E–280–2001/0).

hMPV Technology

(1) U.S. patent application, serial number 10/789,400 (filed February 27,

2004) and associated foreign rights from PCT/US04/05881 (filed February 27, 2004) (HHS references E–093–2003/0,1,2)

to MedImmune, LLC, having a place of business in Gaithersburg, Maryland, USA. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before November 7, 2008 will be considered.

ADDRESSES: Requests for a copy of the patents and patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; e-mail: *shmilovm@mail.nih.gov*; Telephone: (301) 435–5019; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty (60) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The above referenced technologies describe development of live, attenuated virus vaccines for respiratory syncytial virus (RSV), subgroups A and B, human parainfluenza, types 1, 2,3 (HPIV1, HPIV2, and HPIV3), and human metapneumovirus (hMPV).

The field of use in which NIH contemplates granting an exclusive license may be limited to the following and excludes fields employing any vectored vaccines and any human-bovine chimeras for RSV A, RSV B, HPIV3, HPIV2, HPIVI, and hMPV:

Live attenuated virus vaccines for intranasal administration to humans against RSV subgroups A and B, HPIV1, HPIV2, HPIV3, and hMPV based on the following viruses (in bold) and their corresponding attenuating mutations (in bulleted *italics*):

Human RSV subgroups A or B or A/B chimeras:

- *rcp248/404/1030ΔSH, including the stabilized version of this virus*;
- *ΔNS1*;
- *ΔM2–2*.

HPIV3

- *rcp45*

HPIV2

- *Mutations in C and L imported from other viruses, e.g., HRSV, BPIV3, and HPIV3, with or without stabilization by codon substitution or deletion;*
- *L(Δ1724)*;
- *Viruses with P and V genes separated*

HPIV1

- *Mutations in C and L imported from other viruses, e.g., HRSV, BPIV3, and HPIV3, with or without stabilization by codon substitution or deletion*;
- *C(170)*;
- *C(R84G) mutation*;
- *L(942stablized)*;
- *Viruses with P and C genes separated*.

hMPV

- *ΔG, alone or in combination with ΔSH*;
- *ΔM2–2*;
- *Avian-human chimera with avian P ORF placed in hMPV backbone*.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 26, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–20650 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Report on Carcinogens (RoC); Request for Public Comments on the RoC Expert Panel's Recommendation on Listing Status for Styrene in the 12th RoC and the Scientific Justification for the Recommendation

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Request for comments.

SUMMARY: The RoC Office invites public comment on the recommendation from an expert panel on the listing status for styrene in the 12th RoC and the scientific justification for the recommendation. The recommendation and scientific justification for styrene is available electronically in Part B of the Expert Panel Report (*http://ntp.niehs.nih.gov/go/29682,* see Expert Panel Report Part B) or in printed text from the RoC Office (see **FOR FURTHER INFORMATION CONTACT** below). The RoC Office convened an eleven-member expert panel of scientists from the public and private sectors on July 21–22, 2008. The panel was asked (1) to apply the RoC listing criteria to the relevant scientific evidence and make a recommendation regarding listing status (i.e., known to be a human carcinogen, reasonably anticipated to be a human carcinogen, or not to list) for styrene in the 12th RoC and (2) to provide the scientific justification for the recommendation.

DATES: The Expert Panel Report (Part B) for styrene will be available for public comment by September 3, 2008. Written comments should be submitted by October 23, 2008.

ADDRESSES: Comments should be sent to Dr. Ruth Lunn, Director, RoC Office [NIEHS, P.O. Box 12233, MD EC–14, Research Triangle Park, NC 27709, Fax: 919–541–0144, or *lunn@niehs.nih.gov.* Courier address: Report on Carcinogens, 79 T.W. Alexander Drive, Building 4401, Room 3118, Research Triangle Park, NC 27709].

FOR FURTHER INFORMATION CONTACT: Dr. Ruth Lunn, RoC Office, 919–316–4637 *lunn@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Styrene is a flammable liquid used worldwide in the manufacture of polystyrene, which is used extensively in the manufacture of plastic packaging, thermal insulation in building construction and refrigeration equipment, and disposable cups and containers. Styrene also is used in other polymers and resins that are used to manufacture boats, shower stalls, tires, automotive parts, and many other products. The general population is exposed to styrene from inhalation of indoor air; and outdoor air, tobacco smoke, and ingestion of food. Occupational exposure occurs mainly in the reinforced plastics, styrene-butadiene rubber, and styrene monomer and polymer industries.

As part of the RoC review process (available at *http://ntp.niehs.nih.gov/go/15208),* the NTP announced the availability of the draft background document for styrene (**Federal Register**: May 20, 2008: Vol. 73, No. 98, pages 29139–29140), invited public comments

on the draft background document, and announced the styrene expert panel meeting. The RoC Office convened an eleven-member expert panel of scientists from the public and private sectors to evaluate styrene. The expert panel met on July 21–22, 2008, in a public forum at the Radisson Governors Inn, Research Triangle Park, North Carolina. The panel was charged to peer review the draft background document for styrene and then to make a recommendation on its listing status in the 12th RoC and to provide a scientific justification for that recommendation. Details about the meeting, including public comments received and the expert panel reports, are available on the RoC Web site (*http://ntp.niehs.nih.gov/go/29682).* The expert panel report for styrene contains two parts: Part A contains the peer-review comments on the draft background document and Part B is the recommendation on listing status and its scientific justification. The expert panel recommended that (1) styrene be listed in the 12th RoC as reasonably anticipated to be a human carcinogen. The panel's recommendation on listing status and its scientific justification are now being released for public comment.

Request for Comments

The RoC Office invites written public comments on the expert panel's recommendation on listing status for styrene and the scientific justification for the recommendation. All comments received will be posted on the RoC Web site. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Lunn (see **ADDRESSES** above). The deadline for submission of written comments is October 23, 2008.

Next Steps

The RoC Office is in the process of finalizing the background document for styrene based upon the expert panel's peer review comments and the public comments received (73 FR 29139). Persons can register free-of-charge with the NTP listserve (*http://ntp.niehs.nih.gov/go/231*) to receive notification when the final background document is posted on the RoC Web site (*http://ntp.niehs.nih.gov/go/10091*). As part of the RoC review process, two government groups will also conduct reviews of styrene; these meetings are not open to the public. Upon completion of these reviews, the NTP will (1) draft a substance profile for styrene, which contains its listing recommendation for the 12th RoC and the scientific information supporting that recommendation; (2) solicit public comment on the draft substance profile; and (3) convene a meeting of the Board of Scientific Counselors to peer review the draft substance profile.

Background Information on the RoC

The RoC is a Congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as ''substances'') that may pose a hazard to human health by virtue of their carcinogenicity. The RoC follows a formal, multi-step process for review and evaluation of selected chemicals. Substances are listed in the report as either known or reasonably anticipated human carcinogens. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. Information about the RoC and the review process is available on its Web site (*http://ntp.niehs.nih.gov/go/roc*) or by contacting Dr. Lunn (see **FOR FURTHER INFORMATION CONTACT** above).

Dated: August 29, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–20777 Filed 9–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Entry and Manifest of Merchandise Free of Duty

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing information collection: 1651–0013.

ACTION: Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Entry and Manifest of Merchandise Free of Duty. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 36544) on June 27, 2008, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before October 8, 2008.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13).

Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections 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, e.g., permitting electronic submission of responses.

Title: Entry and Manifest of Merchandise Free of Duty.

OMB Number: 1651–0013.

Form Number: CBP Form–7523.

Abstract: CBP Form–7523 is used by carriers and importers as a manifest for the entry of merchandise free of duty under certain condition and by CBP to authorize the entry of such merchandise. It is also used by carriers to show that the articles being imported

are to be released to the importer or consignee.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 4,950.

Estimated Number of Responses per Respondent: 20.

Estimated Number of Total Annual Responses: 99,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 8,247.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: August 26, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–20769 Filed 9–5–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing information collection: 1651–0051

ACTION: Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 36542) on June 27, 2008, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before October 8, 2008.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION:

U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections 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, e.g., permitting electronic submission of responses.

Title: Foreign Trade Zone Annual Reconciliation Certification and Record Keeping Requirement.

OMB Number: 1651–0051.

Form Number: N/A.

Abstract: Each Foreign Trade Zone Operator will be responsible for maintaining its inventory control in compliance with statute and regulations. The operator will furnish CBP an annual certification of their compliance.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 260.

Estimated Time per Respondent: 45 minutes.

Estimated Total Annual Burden Hours: 195.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: August 26, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–20770 Filed 9–5–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Agency Information Collection Activities: Petition for Remission or Mitigation of Forfeitures and Penalties Incurred

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing information collection: 1651–0100.

ACTION: Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Petition for Remission or Mitigation of Forfeitures and Penalties Incurred. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (73 FR 36546) on June 27, 2008, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is

conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before October 8, 2008.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to*oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION:

U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections 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, *e.g.*, permitting electronic submission of responses.

Title: Petition for Remission or Mitigation of Forfeitures and Penalties.

OMB Number: 1651–0100.

Form Number: CBP Form 4609.

Abstract: Persons whose property is seized or who incur monetary penalties due to violations of the Tariff Act are entitled to seek remission or mitigation by means of an informal appeal. This form gives the violator the opportunity to claim mitigation and provides a record of such.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 28,000.

Estimated Number of Responses per Respondent: 1.

Estimated Time per response: 14 minutes.

Estimated Total Annual Burden Hours: 6,500.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: August 26, 2008.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E8–20763 Filed 9–5–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Announcement of Termination of National Customs Automation Program (NCAP) Test: Semi-Monthly Statement Processing Prototype

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces U.S. Customs and Border Protection's decision to formally terminate the test of the semi-monthly filing and statement processing prototype program that was initiated in April 1998, as part of the National Customs Automation Program. The test of the semi-monthly filing program was conceived as a transitional procedure from the Automated Commercial System to the full electronic processing of commercial importations in the Automated Commercial Environment, which allows account holders to pay duties, taxes, fees, and other payments owed using a periodic statement cycle. The Automated Commercial Environment portal system for Periodic Monthly Payment statement processing has been deployed nationwide thereby ending the need for the semi-monthly filing program.

DATES: *Effective Date*: September 8, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Taylor, Program Officer, Revenue Policy and Programs Branch, ADCVD/Revenue Division, Office of International Trade, U.S. Customs and Border Protection at (202) 863–6527 or via e-mail at *Sharon.Taylor@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Title VI of the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (December 8, 1993), contains provisions pertaining to Customs Modernization (107 Stat. 2170). Subtitle B of Title VI establishes the National Customs Automation Program (NCAP)—an automated and electronic system for the processing of commercial importations. Pursuant to the provisions of Subtitle B, U.S. Customs and Border Protection (''CBP'') developed a new commercial processing system, the Automated Commercial Environment (''ACE''), which is phasing out the Automated Commercial System (''ACS'').

As an interim measure, while the ACS was still in use for the filing of duties, taxes, fees and other payments, the former Customs Service (now CBP) published a General Notice entitled ''Announcement of National Customs Automation Program Test: Semi-Monthly Statement Processing Prototype'' in the **Federal Register** (63 FR 15259) on March 30, 1998, pursuant to section 101.9(b) of CBP regulations (19 CFR 101.9(b)), which implemented the NCAP testing procedures. The prototype permitted importers to file entry summaries and to pay their duties, taxes, and fees within seven days of the end of a fifteen or sixteen day semi-monthly period for cargo released during that period. Pursuant to section 1505 of the United States Code (19 U.S.C. 1505), the interest rate was calculated using the rate in effect seven days after the fifteen or sixteen day semi-monthly period. It provided for suspension of a participant for misconduct and an appeal process. Only six importers elected to participate in the program. The notice originally instituted the program at only 14 ports of entry. The notice stated that the semi-monthly filing and statement processing prototype would be implemented over an 18-month period and would end when the periodic payment/statement feature of ACE was available.

However, ACE was not fully implemented in 2002 and the testing of the semi-monthly processing prototype was incomplete. The reasons for these developments were many, namely, budgeting difficulties, the occurrence of other national events, which occasioned a shifting of CBP priorities, the continuing reorganization of Customs, etc. Furthermore, evaluations of the prototype conducted with participants showed a concern that the prototype testing should be expanded to additional ports so that the national

effect of this program could be fully gauged. The test was not opened to any new participants, but the original six participants continued in the program. As the test program continued, a series of notices announced changes or modifications to the test program in the following notices published in the **Federal Register**: 67 FR 39098 (June 6, 2002); 69 FR 5362 (February 4, 2004); 69 FR 54302 (September 8, 2004); 70 FR 5199 (February 1, 2005); 70 FR 45736 (August 8, 2005); 70 FR 55623 (September 22, 2005) and 71 FR 3315 (January 20, 2006). The development of this NCAP test is set forth in these prior notices.

Termination of National Customs Automation Program Test on the Semi-Monthly Statement Processing Prototype

The periodic monthly payment statement ACE-based process, referenced above, has now exceeded over two billion dollars in revenues on the periodic deposit of estimated duties and fees. All of the six original participants in the ''Semi-Monthly Statement Processing Prototype'' have terminated their involvement in the program in favor of participation in the ACE-based process. The Automated Commercial Environment portal system for Periodic Monthly Payment statement processing has been deployed nationwide thereby ending the need for the semi-monthly filing program. Therefore, this notice formally announces the termination of the ''Semi-Monthly Statement Processing Prototype'' under the NCAP.

Dated: September 3, 2008.

Jason P. Ahern,

Acting Commissioner, U. S. Customs and Border Protection.

[FR Doc. E8–20765 Filed 9–5–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–R–2008–N0173, 80230–1265–0000–S3]

San Luis and Merced National Wildlife Refuges and Grasslands Wildlife Management Area, Merced County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare a comprehensive conservation plan and environmental assessment; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), intend to prepare a Comprehensive Conservation Plan (CCP) and Environmental Assessment (EA) for San Luis and Merced National Wildlife Refuges (NWRs) and the Grasslands Wildlife Management Area (WMA) located in Merced County, California. We provide this notice in compliance with our CCP policy to advise other Federal and State agencies, Tribes, and the public of our intentions, and to obtain suggestions and information on the scope of issues to consider in the planning process.

DATES: To ensure consideration, we must receive your written comments by October 23, 2008.

ADDRESSES: Send your comments or requests for more information by any of the following methods.

E-mail: Sandy_Osborn@fws.gov. Include ''San Luis CCP'' in the subject line of the message.

Fax: Attn: Ms. Sandy Osborn, (916) 414–6497.

U.S. Mail: California and Nevada Region, Refuge Planning, U.S. Fish and Wildlife Service, 2800 Cottage Way, W–1832, Sacramento, California 95825.

In-Person Drop off: You may drop off comments during regular business hours 8 a.m. to 4:30 p.m., Monday through Friday, at San Luis NWR Complex Headquarters, 947 West Pacheco Blvd., Suite C, Los Banos, California.

FOR FURTHER INFORMATION CONTACT: Ms. Sandy Osborn, Planning Team Leader, at (916) 414–6503.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we initiate our process for developing a CCP for San Luis and Merced NWRs and the Grasslands WMA in Merced County, CA. This notice complies with our CCP policy to: (1) Advise other Federal and State agencies, Tribes, and the public of our intention to conduct detailed planning on this refuge and (2) obtain suggestions and information on the scope of issues to consider in the environmental document and during development of the CCP.

Background

The CCP Process

The National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–668ee) (Improvement Act), which amended the National Wildlife Refuge System Administration Act of 1966, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Improvement Act.

Each unit of the National Wildlife Refuge System is established for specific purposes. We use these purposes as the foundation for developing and prioritizing the management goals and objectives for each refuge within the National Wildlife Refuge System mission, and to determine how the public can use each refuge. The planning process is a way for us and the public to evaluate management goals and objectives that will ensure the best possible approach to wildlife, plant, and habitat conservation, while providing for wildlife-dependent recreation opportunities that are compatible with each refuge's establishing purposes and the mission of the National Wildlife Refuge System.

Our CCP process provides participation opportunities for Tribal, State, and local governments; agencies; organizations; and the public. At this time we encourage input in the form of issues, concerns, ideas, and suggestions for the future management of San Luis and Merced NWRs and the Grasslands WMA.

We will conduct the environmental review of this project in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*); NEPA regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; and our policies and procedures for compliance with those laws and regulations.

San Luis and Merced NWRs and Grasslands WMA

The San Luis and Merced NWRs and Grasslands WMA are in Merced County, California, adjacent to the communities of Los Banos and Merced. They are situated within the San Joaquin River watershed in the San Joaquin Valley.

Collectively, these three units of the National Wildlife Refuge System contain one of the largest contiguous freshwater wetlands remaining in California, which provides important winter habitat for millions of migratory birds, as well as assemblages of other

native wetland- and grassland-dependent wildlife.

The Merced NWR was established in 1951 and consists of 10,262 acres. The San Luis NWR was established in 1967 and consists of 26,878 acres. The Grasslands WMA was established in 1979 and contains more than 190 privately-owned parcels under Service conservation easements totaling approximately 90,000 acres, within an approved acquisition boundary of 230,000 acres.

Public Availability of Comments

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.

Dated: August 18, 2008.

Richard F. Kearney,

Acting Regional Director, California and Nevada Region, Sacramento, California.

[FR Doc. E8–19488 Filed 9–5–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU81172]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease, Utah

September 2, 2008.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with Title IV of the Federal Oil and Gas Royalty Management Act (Pub. L. 97–451), Delta Petroleum Corporation timely filed a petition for reinstatement of oil and gas lease UTU81172 for lands in Grand County, Utah, and it was accompanied by all required rentals and royalties accruing from April 1, 2008, the date of termination.

FOR FURTHER INFORMATION CONTACT: Kent Hoffman, Deputy State Director, Division of Lands and Minerals at (801) 539–4080.

SUPPLEMENTARY INFORMATION: The Lessee has agreed to new lease terms for rentals and royalties at rates of $10 per acre and 16⅔ percent, respectively. The $500 administrative fee for the lease has been paid and the lessee has reimbursed the Bureau of Land Management for the cost of publishing this notice.

Having met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate the lease, effective April 1, 2008, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Kent Hoffman,

Deputy State Director, Division of Lands and Minerals.

[FR Doc. E8–20696 Filed 9–5–08; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places;Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before August 23, 2008.

Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St., NW., 8th floor, Washington DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by September 23, 2008.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

ALABAMA

Montgomery County

Frazier Hill, 6716 Old Selma Rd., Antioch, 08000951

ARKANSAS

Drew County

Ridgeway Hotel Historic District, 200–206 East Gaines St., Monticello, 08000952

Hempstead County

Southwestern Proving Ground Building #129, (World War II Home Front Efforts in Arkansas) 195 Hempstead Co. Rd. 279, Hope, 08000953

Jackson County

Erwin Auxiliary Army Airfield (World War II Home Front Efforts in Arkansas), NE. of AR 14 and Jackson Rd. 917 jct., Newport, 08000954

Sebastian County

Greenwood Presbyterian Church, 103 W. Denver St., Greenwood, 08000955

DISTRICT OF COLUMBIA

District of Columbia

Slayton, William L., House, 3411 Ordway St., NW., Washington DC, 08000956

FLORIDA

St. Johns County

Fort Matanzas NM Headquarters and Visitor Center (Florida's New Deal Resources MPS), 8635 A1A S., St.Augustine, 08000957

ILLINOIS

Cook County

Cicero Fire House No. 2, 129 Lake St., Oak Park, 08000959

Sauganash Historic District, Bounded on the W. by the former alley to the W. of Kilpatrick Ave., Hiawatha Ave., andKeating Ave., Chicago, 08000958

MISSOURI

Jackson County

Aines Farm Dairy Building, 3110–30 Gillham Rd., Kansas City, 08000960

TEXAS

Hall County

Hall County Courthouse, 512 W. Main, Memphis, 08000961

Hidalgo County

M and J Nelson Building, 300–308 S. 14th St., McAllen, 08000962

WISCONSIN

Richland County

Shadewald II Mound Group, (Late Woodland Stage in Archeological Region 8 MPS) Address Restricted, Town of Eagle, 08000963

[FR Doc. E8–20680 Filed 9–5–08; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–648]

In the Matter of Certain Semiconductor Integration Circuits Using Tungsten Metallization and Products Containing Same; Notice of Commission Decision Not To Review an Initial Determination Granting Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade

Commission has determined not to review an initial determination (''ID'') (Order No. 12) of the presiding administrative law judge (''ALJ'') granting a joint motion to amend the complaint and the notice of investigation in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 21, 2008 based on a complaint filed on April 18, 2008 by LSI Corporation of Milpitas, California and Agere Systems Inc. of Allentown, Pennsylvania. 73 FR 29534–35 (May 21, 2008). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor integrated circuits using tungsten metallization and products containing same by reason of infringement of claim 1 of U.S. Patent No. 5,227,335. The complaint named numerous respondents including NXP B.V. of the Netherlands. The complaint further alleged that an industry in the United States exists as required by subsection (a)(2) of section 337.

On June 30, 2008, complainants, NXP B.V. and proposed respondent NXP Semiconductors USA, Inc. (''NXP Semiconductors'') of San Jose, California moved to amend the complaint and notice of investigation to substitute NXP Semiconductors for NXP B.V. No party opposed the motion.

On August 8, 2008, the ALJ issued the subject ID granting the joint motion to amend. No party petitioned for review of the ID. The Commission has determined not to review this ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in sections 210.14 and 210.42(c) of the Commission's Rules of Practice and Procedure, 19 CFR 210.14, 210.42(c).

Issued: September 2, 2008.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–20751 Filed 9–5–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–08–026]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: September 11, 2008 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: none
2. Minutes
3. Ratification List
4. Inv. No. 731–TA–1123 (Final) (Steel Wire Garment Hangers from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioner's opinions to the Secretary of Commerce on or before September 22, 2008.)
5. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: September 2, 2008.

By order of the Commission.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E8–20664 Filed 9–5–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–08–027]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: September 12, 2008 at 11 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None
2. Minutes
3. Ratification List
4. Inv. Nos. 701–TA–458 and 731–TA–1154 (Preliminary) (Certain Kitchen Appliance Shelving and Racks from China)—briefing and vote. (The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before September 15, 2008; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before September 22, 2008.)
5. Inv. Nos. 731–TA–1124 and 1125 (Final) (Electrolytic Manganese Dioxide from Australia and China)—briefing and vote. (The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before September 22, 2008.)
6. Outstanding action jackets: None

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: September 2, 2008.

By order of the Commission.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E8–20665 Filed 9–5–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting Notice No. 8–08]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of Commission business and other matters specified, as follows:

DATE AND TIME: Wednesday, September 17, 2008, at 10:30 a.m.

SUBJECT MATTER: Issuance of Proposed Decisions, Amended Proposed Decisions, and Orders in claims against Albania.

STATUS: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Room 6002, Washington, DC 20579. Telephone: (202) 616–6988.

Mauricio J. Tamargo,

Chairman.

[FR Doc. E8–20879 Filed 9–4–08; 4:15 pm]

BILLING CODE 4410–01–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,448]

Prestolite Wire LLC, Including On-Site Leased Workers From Talent Tree, Tifton, GA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on June 10, 2008, applicable to workers of Prestolite Wire LLC, including on-site leased workers of Talent Tree, Tifton, Georgia. The notice was published in the **Federal Register** on June 27, 2008 (73 FR 36575).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of automotive ignition wire assemblies.

Findings show that there was a previous certification, TA–W–59,531, issued on July 13, 2006, for the workers of Prestolite Wire LLC, Tifton, Georgia. That certification expired on July 13, 2008. To avoid an overlap in worker group coverage for the workers of the Tifton, Georgia location, the certification is being amended to change the impact date from May 29, 2007 to July 14, 2008.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Prestolite Wire LLC who were adversely affected by a shift in production of automotive ignition wire assemblies to Mexico.

The amended notice applicable to TA–W–63,448 is hereby issued as follows:

All workers of Prestolite Wire LLC, including on-site leased workers from Talent Tree, Tifton, Georgia, who became totally or partially separated from employment on or after July 14, 2008, through June 10, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 28th day of August 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20690 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–54,455]

Weirton Steel Corporation, Weirton, WV; Negative Determination on Remand

On April 30, 2008, the U.S. Court of International Trade (USCIT) remanded *United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, Local 2911* v. *United States Secretary of Labor*, Court No. 04–00492, to the U.S. Department of Labor (Department) for further investigation.

On March 9, 2004, an official of Weirton Steel Corporation (subject firm) filed a petition for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) on behalf of workers of Weirton Steel Corporation, Weirton, West Virginia (subject facility). AR 2. Workers at the subject facility produce hot-rolled, cold-rolled, tin-plate and hot-dipped, and electrolytic galvanized steel. AR 2, 48. The workers are not separately identifiable by specific product. AR 48.

On April 23, 2002, workers at Weirton Steel Corporation, Weirton, West Virginia were certified eligible to apply for TAA (TA–W–39,657; certification was issued on April 23, 2002 and expired on April 23, 2004). SAR 18.

The initial investigation revealed that the subject firm neither imported steel products nor shifted steel production to a foreign country in the one year prior to the petition date (March 9, 2003 through March 9, 2004). AR 102. The initial investigation also revealed that although subject firm production declined in 2003 from 2002 levels and declined during January through February 2004 compared with the corresponding period in 2003, subject firm sales increased in 2003 compared with 2002, and increased in January through February 2004 compared with the corresponding period in 2003. AR 102.

The Department surveyed fifteen of the subject firm's major declining customers regarding their purchases of the principal product types of steel sold by the subject firm in 2002, 2003, January through March 2003, and January through March 2004. The majority of respondents reported either no imports or declining imports. The survey also revealed that for those customers that did increase import purchases, the imports were substantially less than one percent of the subject firm's sales or production. AR 102.

Aggregate data of the major steel products manufactured by the subject facility during the relevant period (hot-rolled carbon sheet, cold-rolled carbon sheet, hot-dipped galvanized sheet and strip, galvanized electrolytic carbon sheet and strip, and tin mill products) indicated that imports of these products declined, both absolutely and relative to shipments, in 2003 compared with 2002, and continued to decline in the first quarter of 2004 compared with the corresponding period of 2003. AR 102.

The Department's negative determination regarding the subject workers' eligibility to apply for worker adjustment assistance was issued on May 14, 2004. AR 103. The Department's Notice of determination was published in the **Federal Register** on June 2, 2004 (69 FR 31135). AR 104.

By letter dated June 18, 2004, the Independent Steelworkers Union (ISU), via their counsel, requested administrative reconsideration of the Department's negative determination applicable to the subject workers. AR 119. The ISU requested that the investigation period be extended in order to include information regarding subject firm sales declines and import impact that were the basis for an expired TAA certification (TA–W–39,657; certified on April 23, 2002). AR 119–194.

The Notice of Negative Determination Regarding Application for Reconsideration (issued on July 23, 2004) stated that information on events that occurred before the relevant period cannot be the basis for TAA certification in the immediate case. AR 195. The Department's Notice of determination

was published in the **Federal Register** on August 4, 2004 (69 FR 47184). AR 198.

By letter dated September 14, 2004, the Independent Steelworkers Union (ISU) requested that the expired certification for TA–W–39,657 be amended to include workers separated from the subject facility after the end of the original certification period (April 23, 2004). SAR 12.

The request for amendment stated that, on May 18, 2004, ''substantially all of the production assets of Weirton Steel Corporation were acquired out of bankruptcy by International Steel Group, Inc. (ISG)'' and ''Weirton ceased to exist as a producer of steel and several hundred additional employees were permanently separated from the company.'' SAR 13. The letter asserts that the intent of the request is to provide TAA eligibility to those workers who stayed with the subject firm after the expiration of the certification in order to effectuate the sale of assets, which took place on May 18, 2004. SAR 12. In support of the request, the ISU cited two cases in which the Department extended the certification date (*O/Z–Gedney Co.*, Division of EGS Electrical Group, Terrytown, Connecticut; TA–W–38,569 and *Wiegand Appliance Division, Emerson Electric Company*, Vernon, Alabama; TA–W–39,436). SAR 14.

On September 24, 2004, the Department issued a letter in which the Plaintiff was notified that its request had been denied. The letter explained that the Department extends the certification period, before it expires, in those cases where workers were retained beyond the certification period in order to assist with the closure of the facility after production had ceased. The Department's letter stated:

> You referred to two trade petition certifications where the expiration dates were extended, specifically, O/Z Gedney Company, Division of EGS Electrical Group, Terryville, Connecticut (TA–W–38,569) and Wiegand Appliance Division, Emerson Electric Company, Vernon, Alabama (TA–W–39,436). In each of these cases, workers were retained to assist with the plant closure after production had ceased. That is not the case for workers at Weirton Steel. Production of steel products at the Weirton, West Virginia plant continued during the period relevant to the investigation.

SAR 16–17.

By letter to the USCIT, dated October 1, 2004, the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, Local 2911 (Plaintiff) sought judicial review of the July 23, 2004 determination denying reconsideration in this matter.

The complaint stated that the Plaintiff's challenges are ''(1) the final determination in the investigation regarding certification of eligibility of former employees of Weirton Steel Corporation, Weirton, West Virginia, to apply for worker adjustment assistance, Case No. TA–W–54,455, and (2) the final negative determination in response to a request for an amendment of the certification in Case No. TA–W–39,657 to extend the expiration date of that certification from April 23, 2004 to May 18, 2004, so as to guarantee eligibility for all former employees of Weirton Steel who were adversely affected by increased imports.''

Plaintiff's first claim is that ''the Department's use of a one-year 'representative base period' in this case ignored the reality that in certain industries, such as steel, there was the possibility or even the likelihood of a lag time of more than one or two years between import surges and workers separations.''

Plaintiff's second claim is that the Department has much discretion as to how it gathers and analyzes information in determining whether increased imports contributed importantly to worker separations, and that regulations should not be construed as a ''bar to a more expansive inquiry where there are compelling reasons for a broader examination.''

Plaintiff's third claim is that the Department is not precluded by the statute or the regulation from considering ''only imports during the two years prior to the date of the petition, or during any particular period of time.''

Plaintiff's fourth claim is that while amendments are absent in both the statute and the regulation, the Department has not supported its decision (to not extend the certification period to May 18, 2004) with substantial evidence and has failed to reconcile the decision with other cases where requests for amendments to extend the period of certification were granted.

The Department filed its administrative record with the USCIT supporting its decision. On November 17, 2006, the USCIT issued its opinion which sustained the Department's negative determination applicable to TA–W–54,455. The USCIT also stated that it possessed jurisdiction to review the Department's decision not to grant the request to extend the certification of TA–W–39,657 and that it was reserving judgment pending the Department's submission of additional documentation related to the amendment request. The court remanded the case to the Department ''with instructions to assemble and submit to the court the administrative record regarding plaintiff's amendment claim.'' Slip. Op. at 31. On January 27, 2007, the Department filed a supplemental administrative record with the USCIT in accordance with that order.

In its April 30, 2008 remand order, the Court considered the Department's decision, in addition to the Department's supplemental administrative record, which refused to extend the prior determination and remanded the matter to the Department for it to provide a fuller explanation of its refusal to extend the certification. The USCIT, in its order, directed the Department to: (1) Clarify the basis of and to fully explain any decision it reaches; (2) establish the facts upon which it makes its determination and state precisely why it is, or is not, significant that the Weirton plant did not close; (3) clearly explain why, if at all, the Weirton workers who lost their jobs after April 23, 2004, should be treated differently than those who lost their jobs prior to that date; (4) set forth its current and past policy regarding amendments to the expiration date of certifications; (5) explain how the case at hand is different, if at all, from previous cases where it extended worker certifications; (6) set forth all steps, if any, taken to change its policy with respect to extensions, including any measures taken to notify the public, and the dates on which all such steps were undertaken; (7) set forth the criteria upon which it makes any determination to extend or not to extend the subject certification; and (8) explain why its determination is in accord with the remedial nature of the TAA statute.

In order to better explain the Department's determination, the Department has addressed the USCIT's concerns in a different order than above and has included facts relevant to TA–W–39,657 as well as the history of the administration of the Trade program.

Relevant Facts of TA–W–39,657

On April 23, 2002, the Department issued a certification applicable to workers and former workers of Weirton Steel Corporation, Weirton, West Virginia (TA–W–39,657) who produced hot and cold rolled coated carbon steel. The certification was based on the finding that, during the relative period, sales, production, and employment at the subject firm decreased while ''U.S. aggregate imports of cold-rolled carbon steel sheet increased both absolutely and relative to domestic shipments'' during the relative period. SAR 18–19.

In May 2003, Weirton filed for bankruptcy. AR 122, SAR 13. During this bankruptcy proceeding, Weirton agreed to sell to ISG (a competitor) its assets, including steel production equipment at the Weirton, West Virginia location. SAR 13. During the transition period between the bankruptcy filing and the sale of its assets to ISG, over three hundred workers employed by Weirton, AR 2, 46, 50, 96, continued to produce steel at the Weirton, West Virginia facility. AR 49–50, SAR 13–14. After the sale took place, on May 18, 2004, ISG took over production at the Weirton, West Virginia facility and Weirton separated the workers remaining at the West Virginia facility. SAR 13–14.

Applicable Authorities

Under Section 222(a) of the Trade Act of 1974, as amended, a worker group is adversely-affected by increased imports if (1) A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated; (2) the sales and/or production of such firm or subdivision have decreased absolutely; and (3) increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision. This is codified in 29 CFR 90.16.

Under section 223(d) of the Trade Act, the Secretary is authorized to terminate a certification ''[w]henever the Secretary determines * * * that total or partial separations from such firm or subdivision are no longer attributable to the conditions specified in section 222.'' This is codified in 29 CFR 90.17.

Under Section 231 of the Trade Act, payment of a Trade Readjustment Allowance (TRA) shall be made to an adversely affected worker covered by a certification under conditions including that the worker's separation occurred on or after the beginning date of the certification and ''before the expiration of the two-year period beginning on the date on which the determination * * * was made'' or an earlier date if the Department terminates the certification prior to the end of that period. This is codified in 20 CFR 617.11.

The TAA Certification Period

Historically, the Department issued certifications that did not expire until two years after the issuance of the certification; however, if the facts of a case indicated that worker separations would conclude on a date earlier than two years from the date of the certification (such as in a plant closure), the Department would issue a certification that contained a termination date that corresponded to the latest date that, based on the information provided by the company, the Department determined that workers' separations could be attributable to the basis for the certification.

Applying the statutory guidance in section 223(d) of the Trade Act, where the facts of a case indicate that the worker separations will conclude earlier than the 2-year expiration of the certification, the Department has terminated certifications, which resulted in certifications with a shorter eligibility period than the ''2-year expiration date.''

Section 231 of the Trade Act provides that payment of a Trade Readjustment Allowance (TRA), which is the largest benefit available under the Trade Act, shall be made to an adversely affected worker covered by a certification if the worker's separation occurred on or after the beginning date of the certification and ''before the expiration of the two-year period beginning on the date on which the determination * * * was made'' or an earlier date if the Department terminates the certification prior to the end of that period. Utilizing the 2-year expiration date in certifications is consistent with this section of the Trade Act.

As the TAA program evolved, the Department addressed the issue of termination of the certification period in Unemployment Insurance Program Letter 28–80 (April 9, 1980). This guidance to state agencies that determine individual eligibility for TAA benefits states that a certification which is amended to add new groups of workers, which could have been included in the original certification, should not extend the two-year period of the certification.

Currently, the Department continues to issue certifications that do not expire until two years after the date of the determination and does not monitor certified worker groups to ascertain whether the worker separations are attributable to the basis for certification.

The Department's Current Policy Regarding Amendments to the Expiration Date of Certifications

As stated in all amendment determinations, the intent of the Department is for the certification to cover all workers of the subject firm or appropriate subdivision who were adversely affected by increased imports of the article produced by the firm or a shift in production of the article, based on the investigation of the petition.

Neither the statute nor the regulation addresses whether the Department may amend certifications or how to process requests for amendments, although section 223(d) of the Trade Act and 29 CFR 90.17 authorize the Department to terminate certifications if, after an investigation, the Department believes that worker separations are ''no longer attributable to the conditions specified in section 222 of the Trade Act and 29 CFR 90.16(b).'' However, in implementing its authority to certify all adversely affected workers, the Department has and continues to amend the expiration date of certifications when the facts of the case show that the later worker separations are attributable to the basis for certification (the increased imports or shift of production to a foreign country).

Because terminating a certification denies a previously-eligible worker group's access to an entitlement program, the Department believes that using a standard for amending a certification to include a previously-excluded worker group that is identical to the approved standard for terminating a certification adequately safeguards the interests of the worker group and is in line with the remedial nature of the Trade Act. Therefore, requests to amendment certification to extend the expiration period are granted in cases where the Department determines that the worker separations are ''attributable'' to the basis for the earlier certification.

The Department's policy is reflected in its determination in Thomson, Inc., Circleville, Ohio, TA–W–59,118. SAR 22–23. In *Thomson*, workers alleged that they were part of the worker group certified under TA–W–52,274, issued on August 7, 2003. Thomson continued to employ several workers at the subject facility after August 7, 2005, the expiration date that certification, although production had ceased when the plant closed on June 25, 2004. The Department explained in the determination that ''the workers who continued their employment with the subject firm to * * * complete shutdown functions are part of the worker group covered by TA–W–52,274.'' The basis for the determination was the Department's finding of ''the causal nexus between the subject facility's closure and the workers' separations.''

The amended certification of TA–W–52,274 (issued January 25 2007) stated ''during the ensuing remand process for TA–W–59,118, the Department

determined that there was a causal nexus between the subject firm's shutdown of operations and the shutdown workers' separations and that, therefore, the separations of the workers * * * are attributable to the conditions specified in section 222 of the Trade Act.'' SAR 22–23.

The Department's Past Policy Regarding Amendments to the Expiration Date of Certification

There has been no change in the Department's policy as to situations such as the one presented in this case. While the Department anticipated a change in its policy to extend the expiration date of a certification beyond two years, that policy has not changed, as shown by the Thomson certification. The Department has not, to the best of our knowledge, amended a certification to extend the expiration date except in limited circumstances when there has been a plant closing and a small number of workers are retained past the 2-year expiration date to complete shutdown activities. The intent of the Department in these cases, as in all cases, is for the amended certification to cover all adversely affected workers at the subject firm or appropriate subdivision (based on the investigation of the petition).

The Department's Steps To Change Policy Regarding Certification Extensions and To Notify the Public of Policy Changes

The Department has not taken any steps to notify the public of any change in policy because there has been no policy change. The Department had intended to amend its certification regulations, as reported in the Department's regulatory agenda, but Congressional action has barred agency action on such regulations. See Section 110 of Division G of Public Law 110–161 (Consolidated Appropriations Act, 2008), which states:

SEC. 110. None of the funds made available in this or any other Act shall be available to finalize or implement any proposed regulation under the Workforce Investment Act of 1998, Wagner-Peyser Act of 1933, or the Trade Adjustment Assistance Reform Act of 2002 until such time as legislation reauthorizing the Workforce Investment Act of 1998 and the Trade Adjustment Assistance Reform Act of 2002 is enacted.

As a result of this prohibition, the Department has been unable to notify the public of any proposal regarding procedures on group eligibility terminations, including procedures on amendments to certifications, and no regulatory change has taken place. The Department shall, however, notify the public of any regulatory proposal and seek public comments on the draft regulations once permissible.

Criteria for Extending Worker Group Certification Period

Requests for an amendment to extend the period of a certification are rare. However, in response to each request for such an amendment to a certification, the Department reviews the facts of the case and determines whether or not it has been demonstrated that the worker separations that occurred after the expiration date of the certification has expired are also ''attributable'' to the basis for that certification. As stated in *Thomson*, the Department must determine that workers separated after the certification expired are appropriately part of the worker group covered by the certification. As such, the earlier and later separated workers must have identical characteristics (same location, same article, and same basis for certification) aside from dates of separation. It must also be shown that the predominant important cause of the later worker separations is identical to the conditions that were the basis for the certification of the earlier separated workers.

If the certification was based on increased imports, the petitioning worker group must show that the increased imports (same article, same time periods, etc.) contributed importantly to their separations; if the certification was based on a shift of production, the petitioning worker group must show that the same shift of production (same article, same country, etc.) was the basis for their separations.

The Significance of the Lack of Closure of the Weirton Plant

When considering whether or not to grant the request to extend the certification period of TA–W–39,657, the Department must determine whether worker separations after April 23, 2004 are attributable to the increased imports that were the basis of the certification of TA–W–39,657. If it is demonstrated that the contributing cause of the worker separations at issue is not the increased imports that were the basis of the certification, amending the certification is not appropriate.

Further, should the Department find that the same conditions that were the basis for certification in TA–W–39,657 persisted beyond April 23, 2004, and that worker separations after April 23, 2004 are attributable to the basis for certification, the Department may extend the certification period. However, if there was a change in circumstance that prevents a causal nexus between the workers' separation and the basis for certification, then the Department cannot find that the workers' separation is attributable to the basis for certification.

If a production facility closes, the workers at that facility would eventually be separated from that facility, and the Department would determine that there was a causal nexus between the workers' separations and the plant closure. The significance of a plant closure was most recently demonstrated in *Thomson*, where the plant closed and the Department amended the certification to include the shutdown workers' separations. However, because the Weirton facility did not close, there is no such causal nexus between the separations and the events that were the basis for the certification of TA–W–39,657.

The investigation of TA–W–54,455 disclosed that the Weirton facility continued production beyond the certification date of TA–W–39,657. AR 2, 46, 50, 96, SAR 13–14. Accordingly, the facility ceased to suffer from the same economic conditions that were the basis for the certification, and the later worker separations are not attributable to the increased imports that were the basis for the TA–W–39,657 certification. In addition, the evidence found in support of the denial of the certification request in the instant case showed that sales of the subject firm increased in the relevant period, and that there were declining imports or little or no increase in imports during the relevant period. AR 102. This negative determination was published in the **Federal Register** on June 2, 2004 (69 FR 31135). AR 104. A review of the record amply demonstrates that extension of the certification of TA–W–39,657 to cover the workers would be contrary to the Department's policy and practice.

Different Treatment of Separations After April 23, 2004 Than Separations That Occurred On or Prior to April 23, 2004

Workers separated after April 23, 2004 are treated differently from those separated on or prior to April 23, 2004, because the workers separated before April 23, 2004 belong to a separately identifiable worker group.

In the case at hand, the Department issued a routine certification that expired two years from the date of issuance because there was no information in the record to indicate that a shorter certification was appropriate. And, because the Department did not conduct a termination investigation, the certification period was not shortened.

Therefore, the issue is not whether the worker separations on or before April 23, 2004 are attributable to the increased imports that were the basis for certification; the issue is whether or not the worker separations after April 23, 2004 are attributable to the increased imports that were the basis for certification.

The Department must determine whether the events that caused the separations after April 23, 2004 are identical to those that were the basis for the certification. While the certification of workers separated on or before April 23, 2004 was based on increased imports, SAR 18–19, worker separations after April 23, 2004 resulted from ISG's decision not to continue to employ the Weirton production workers when it purchased the operating Weirton plant as part of the May 18, 2004 sale. SAR 13–14. Accordingly, the Department determines that workers separated on May 18, 2004, belong in a worker group that is separately identifiable from the worker group covered by the certification in TA–W–39,657, and that the Department's determination denying amendment of the TA–W–39,657 to include both worker groups is appropriate under the circumstances.

Weirton Different From Previous Cases Where the Department Extended Worker Certifications

Plaintiffs allege that the action taken by the Department in the case at hand is inconsistent with the actions taken in *O/Z–Gedney Co., Division of EGS Electrical Group*, Terrytown, Connecticut, TA–W–38,569 (O/Z–Gedney) and *Wiegand Appliance Division, Emerson Electric Company*, Vernon, Alabama, TA–W–39,436 (Wiegand).

In *O/Z–Gedney*, the certified workers were engaged in the production of electrical fittings until the facility closed. The amended certification stated that the intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports. The Department amended the certification because there was a causal nexus between the workers' separation and the plant closure that was the result of increased imports. The single worker retained at the subject firm beyond the March 27, 2003 expiration date was engaged in activities related to the close-down process until her termination on March 26, 2004. SAR 20.

In *Wiegand*, the certified workers were engaged in activities related to the production of electric heating elements until the company closed. The amended certification stated that the intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports. The Department amended the certification because there was a causal nexus between the worker's separation and the plant closure that was the result of increased imports. The workers separated after the July 16, 2003 expiration date were retained to conduct activities related to the closure of the facility. These workers completed the tracking of outstanding customer orders until their termination on July 21, 2003. SAR 21.

In *Thomson*, the amended certification issued by the Department stated that the intent of the certification is to include all workers of the subject firm who were adversely affected by increased imports. The Department stated that there was a causal nexus between the worker's separation and the plant closure. The few workers Thomson continued to employ after the expiration of the certification were retained by the subject firm pursuant to State regulation to engage in decommissioning activities. SAR 24.

As illustrated in the cases discussed above, the Department's amendments were based on findings that increased imports adversely affected the workers separated after the expiration of the certification. The subject firm retained employees past the certification expiration date solely to close down the facility from which the certified workers had been separated based on increased imports of the articles produced at that facility. The Department's treatment of such workers has been consistent and the decision here also is consistent with that practice. The Weirton workers separated after the plant's acquisition by ISG were not engaged in the closedown of that facility, but were actually involved in production and maintenance of the plant.

The Remand Determination Is in Accord With the Remedial Nature of the TAA Statute

In the remand order, the USCIT directs the Department to explain why its determination is in accord with the remedial nature of the Trade Act. The Department respectfully disagrees with the premise of the USCIT's question. While it is true that the Trade Act is remedial in nature, the statute does not authorize the granting of certification, unlimited by time, in every situation involving a sympathetic fact pattern.

Certifications have to end at some time. Our current procedures provide that certifications generally last for two years and are, normally, not terminated short of that. A generous application of the law is not required.

Conclusion

After reconsideration on remand, I affirm the decision not to amend the certification of TA–W–39,657 to include workers separated from Weirton Steel Corporation, Weirton, West Virginia after April 23, 2004.

Signed at Washington, DC, this 28th day of August 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20688 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,197]

Dan River, Inc.; Danville Operations; Danville, VA; Notice of Revised Determination on Reconsideration

On July 11, 2008, the Department issued an Affirmative Determination Regarding Application on Reconsideration applicable to workers and former workers of the subject firm. The notice was published in the **Federal Register** on July 21, 2008 (73 FR 42368).

In the request for reconsideration, the petitioner provided new information regarding production at the subject facility. The petitioner stated that workers of the subject facility produced various package labels and packaging materials.

The Department contacted a company official to address this allegation. Based on information provided by the company official, the Department determined that workers of the subject firm were engaged in the production of package labels and packaging material in 2007 and January through April 2008.

The investigation also revealed that the subject firm has shifted production of package labels and packaging material to China, Pakistan and India impacting workers at the Danville plant. The investigation also revealed that the firm increased imports of package labels and packaging material during the relevant period.

In accordance with Section 246 the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department herein presents the results of its investigation regarding certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers.

In order for the Department to issue a certification of eligibility to apply for

ATAA, the group eligibility requirements of Section 246 of the Trade Act, as amended, must be met. The Department has determined in this case that the requirements of Section 246 have been met.

A significant number of workers at the firm are age 50 or over and possess skills that are not easily transferable. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the facts obtained in the investigation, I determine that there was a shift in production from the workers' firm or subdivision to China, Pakistan and India of articles that are like or directly competitive with those produced by the subject firm or subdivision, and there has been or is likely to be an increase in imports of like or directly competitive articles. In accordance with the provisions of the Act, I make the following certification:

All workers of Dan River, Inc., Danville Operations, Danville, Virginia, who became totally or partially separated from employment on or after April 14, 2007, through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed in Washington, DC, this 27th day of August 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20689 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,903]

Gramercy Jewelry Manufacturing Corp., New York, NY; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 19, 2008 in response to a petition filed by a company official on behalf of workers of Gramercy Jewelry Manufacturing Corp., New York, New York.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 29th day of August 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20687 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,914]

Less Labor, Inc., Hopkinsville, KY, Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 21, 2008 in response to a worker petition filed by a company official on behalf of workers of Less Labor, Inc., Hopkinsville, Kentucky.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 29th day of August 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20691 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,926]

Veyance Technologies, Inc.; Fairlawn, OH; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 25, 2008 in response to a petition filed by a company official on behalf of workers of Veyance Technologies, Inc., Fairlawn, Ohio.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC. this 29th day of August 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–20692 Filed 9–5–08; 8:45 am]

BILLING CODE 4510–FN–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 08–10]

Notice of the September 17, 2008 Millennium Challenge Corporation Board of Directors Meeting; Sunshine Act Meeting

AGENCY: Millennium Challenge Corporation.

TIME AND DATE: 10 a.m. to 11:45 a.m., Wednesday, September 17, 2008.

PLACE: Department of State, 2201 C Street, NW., Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: Information on the meeting may be obtained from Suzi M. Morris via e-mail at *Board@mcc.gov* or by telephone at (202) 521–3600.

STATUS: Meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Board of Directors (the ''Board'') of the Millennium Challenge Corporation (''MCC'') will hold a meeting to discuss and consider country-specific compact development issues and compact implementation issues affecting a number of MCC's countries; and certain administrative matters.

The agenda items are expected to involve the discussion of classified information and the meeting will be closed to the public.

Dated: September 4, 2008.

William G. Anderson, Jr.,

Vice President and General Counsel, Millennium Challenge Corporation.

[FR Doc. E8–20894 Filed 9–4–08; 4:15 pm]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On July 30, 2008, the National Science Foundation published a notice in the **Federal Register** of permit applications

received. A permit was issued on August 29, 2008 to: Judit Hersko, Permit No. 2009–012.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. E8–20628 Filed 9–5–08; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–243]

Oregon State University Triga Reactor; Notice of Issuance of Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of a renewed Facility License No. R–106, to be held by the Oregon State University (OSU or the licensee), which would authorize continued operation of the Oregon State University TRIGA Reactor (OSTR), located in Corvallis, Benton County, Oregon. Therefore, pursuant to 10 CFR 51.21, the NRC is issuing an Environmental Assessment and Finding of No Significant Impact.

Description of Proposed Action

The proposed action is approval of the licensee's application for renewal of Facility License No. R–106 for a period of 20 years from the date of issuance of the renewed license. The proposed action is in accordance with the licensee's application dated October 5, 2004, as supplemented on August 8, 2005, May 24, 2006, November 10, 2006, November 21, 2006, July 10, 2007, July 27, 2007, July 31, 2007, August 6, 2007, April 14, 2008, August 6, 2008 and August 11, 2008.

The OSTR is located in the OSU Radiation Center complex on the west end of the Oregon State University campus and west of downtown Corvallis, OR. Corvallis and OSU lie in Benton County in the Willamette Valley. The OSTR site comprises the area bounded by the Reactor Building fence on the north, Jefferson Way on the south, 35th Street on the west, and the east edge of the OSU Radiation Center complex parking lot on the east. The nearest permanent residence is located 876 feet (267 m) north of the OSTR. There are no nearby industrial, transportation, or military facilities that pose a threat to the OSTR.

The OSTR is a tank-type, light water moderated and cooled research reactor licensed to operate at a steady-state power level of 1.1 megawatts thermal power (MW(t)). The reactor is licensed to operate in a pulse mode, with a maximum reactivity insertion of $2.55. A detailed description of the reactor can be found in the OSTR Safety Analysis Report (SAR). The major modifications to the Facility License were a power uprate to 1.0 MW(t) in June, 1971, and a power uprate to 1.1 MW(t) in December, 1989.

The licensee has not requested any changes to the facility design or operating conditions as part of this renewal request. The proposed action will not increase the probability or consequences of accidents. No changes are being made in the types of effluents that may be released off site. There should be no increase in occupational or public radiation exposure. Therefore, license renewal should not change the environmental impact of facility operation.

Summary of the Environmental Assessment

The NRC staff reviewed the licensee's application which included an Environmental Report. To document its review, the NRC staff has prepared an environmental assessment (EA) which discusses the OSTR site and facility; radiological impacts of gaseous, liquid, and solid effluents; environmental and personnel radiation monitoring; radiation dose estimates for the maximum hypothetical accident (MHA); impacts of the ''no action'' alternative to the proposed action; alternative use of resources; considerations related to the National Environmental Policy Act (NEPA); and presents the radiological and non-radiological environmental impacts of the proposed action.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site *http://www.nrc.gov/reading-rm/adams.html.* For further details with respect to the proposed action, see the licensee's letter dated October 5, 2004, (ADAMS Accession No. ML043270077 and No. ML071430452), as supplemented by letters dated August 8, 2005 (ADAMS Accession No. ML052290051); May 24, 2006 (ADAMS Accession No. ML061510355); November 10, 2006 (ADAMS Accession No. ML063210182); November 21, 2006 (ADAMS Accession No. ML063320500); July 10, 2007 (ADAMS Accession No. ML072150361 and ML072150362); July 27, 2007 (ADAMS Accession No. ML072150363); July 31, 2007 (ADAMS Accession No. ML 072190043); August 6, 2007 (ADAMS Accession No. ML072340580); April 14, 2008 (ADAMS Accession No. ML081150194); August 6, 2008 (ADAMS Accession No. ML082261409); and August 11, 2008 (ADAMS Accession No. ML082270383). Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. The EA can be found in ADAMS under Accession Number ML061650197. 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 at 1–800–397–4209, or 301–415–4737, or send an e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 2nd day of September, 2008.

For the Nuclear Regulatory Commission.

Daniel S. Collins,

Chief, Research and Test Reactors Branch A, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. E8–20699 Filed 9–5–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Week of September 8, 2008.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

ADDITIONAL ITEMS TO BE CONSIDERED:

Week of September 8, 2008

Monday, September 8, 2008

9:30 a.m. Affirmation Session (Public Meeting) (Tentative).

a. U.S. Department of Energy (High Level Waste Repository) DOE's Partially Unopposed Motion for Protective Order Governing Classified Information (filed May 30, 2008). (Tentative).

b. U.S. Department of Energy (High Level Waste Repository: Pre-Application Matters), Docket No. PAPO–00—The DOE's Notice of Appeal from the PAPO Board's April 23, 2008 Order and Nye

County's Motion to File an Amicus Curiae Brief—SRM—SECY–08–0082 (Tentative).

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

Additional Information

By a vote of 4–0 on September 2 and 3, 2008, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that Affirmation of ''a. U.S. Department of Energy (High Level Waste Repository) DOE's Partially Unopposed Motion for Protective Order Governing Classified Information (filed May 30, 2008), and b. U.S. Department of Energy (High Level Waste Repository: Pre-Application Matters), Docket No. PAPO–00—The DOE's Notice of Appeal from the PAPO Board's April 23, 2008 Order and Nye County's Motion to File an Amicus Curiae Brief—SRM—SECY–08–0082'' be held September 8, 2008, and on less than one week's notice to the public.

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html.*

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 *REB3@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 *dkw@nrc.gov.*

Dated: September 3, 2008.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. E8–20838 Filed 9–4–08; 11:15 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

Sunshine Act Meetings

NAME OF AGENCY: Postal Regulatory Commission.

TIME AND DATE: September 15, 2008 at 2 p.m.

PLACE: Commission conference room, 901 New York Avenue, NW., Suite 200, Washington, DC 20268–0001.

STATUS: Open.

MATTERS TO BE CONSIDERED: Fiscal year 2010 budget.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 or *stephen.sharfman@prc.gov.*

Dated: September 4, 2008.

Steven W. Williams,

Secretary.

[FR Doc. E8–20935 Filed 9–4–08; 4:15 pm]

BILLING CODE 7710–FW–P

DEPARTMENT OF STATE

[Public Notice 6350]

Bureau of Economic, Energy, and Business Affairs; Public Notice List of September 8, 2008, of Participating Countries and Entities (Hereinafter Known as ''Participants'') under the Clean Diamond Trade Act of 2003 (Public Law 108–19) and Section 2 of Executive Order 13312 of July 29, 2003

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: In accordance with Sections 3 and 6 of the Clean Diamond Trade Act of 2003 (Pub. L. 108–19) and Section 2 of Executive Order 13312 of July 29, 2003, the Department of State is identifying all the Participants eligible for trade in rough diamonds under the Act, and their respective Importing and Exporting Authorities, and revising the previously published list of January 18, 2008 (Volume 73, Number 13, page 3507–8), to remove Venezuela.

FOR FURTHER INFORMATION CONTACT: Sue Saarnio, Special Advisor for Conflict Diamonds, Bureau of Economic and Business Affairs, Department of State, (202) 647–1713.

SUPPLEMENTARY INFORMATION: Section 4 of the Clean Diamond Trade Act (the ''Act'') requires the President to prohibit the importation into, or the exportation from, the United States of any rough diamond, from whatever source, that has not been controlled through the Kimberley Process Certification Scheme (KPCS). Under Section 3(2) of the Act, ''controlled through the Kimberley Process Certification Scheme'' means an importation from the territory of a Participant or exportation to the territory of a Participant of rough diamonds that is either (i) carried out in accordance with the KPCS, as set forth in regulations promulgated by the President, or (ii) controlled under a system determined by the President to meet substantially the standards, practices, and procedures of the KPCS. The referenced regulations are contained at 31 CFR Part 592 (''Rough Diamonds Control Regulations'') (69 FR 56936, September 23, 2004).

Section 6(b) of the Act requires the President to publish in the **Federal Register** a list of all, and all Importing and Exporting Authorities of Participants, and to update the list as necessary. Section 2 of Executive Order 13312 of July 29, 2003, delegates this function to the Secretary of State. Section 3(7) of the Act defines ''Participant'' as a state, customs territory, or regional economic integration organization identified by the Secretary of State. Section 3(3) of the Act defines ''Exporting Authority'' as one or more entities designated by a Participant from whose territory a shipment of rough diamonds is being exported as having the authority to validate a Kimberley Process Certificate. Section 3(4) of the Act defines ''Importing Authority'' as one or more entities designated by a Participant into whose territory a shipment of rough diamonds is imported as having the authority to enforce the laws and regulations of the Participant regarding imports, including the verification of the Kimberley Process Certificate accompanying the shipment.

List of Participants

Pursuant to Section 3 of the Clean Diamond Trade Act (the Act), Section 2 of Executive Order 13312 of July 29, 2003, and Delegation of Authority No. 294 (July 6, 2006), I hereby identify the following entities as of June 17, 2008, as Participants under section 6(b) of the Act. Included in this List are the Importing and Exporting Authorities for Participants, as required by Section 6(b) of the Act. This list revises the previously published list of January 18, 2008 (Volume 73, Number 35078), to remove Venezuela, as shipments of rough diamonds from Venezuela are not being controlled through the Kimberley Process Certification Scheme at this time.

Angola—Ministry of Geology and Mines.

Armenia—Ministry of Trade and Economic Development.

Australia—Exporting Authority—Department of Industry, Tourism and Resources; Importing Authority—Australian Customs Service.
Bangladesh—Ministry of Commerce.
Belarus—Department of Finance.
Botswana—Ministry of Minerals, Energy and Water Resources.
Brazil—Ministry of Mines and Energy.
Canada—Natural Resources Canada.
Central African Republic—Ministry of Energy and Mining.
China—General Administration of Quality Supervision, Inspection and Quarantine.
Democratic Republic of the Congo—Ministry of Mines.
Republic of Congo—Ministry of Mines.
Croatia—Ministry of Economy.
European Community—DG/External Relations/A.2.
Ghana—Precious Minerals and Marketing Company Ltd.
Guinea—Ministry of Mines and Geology.
Guyana—Geology and Mines Commission.
India—The Gem and Jewelry Export Promotion Council.
Indonesia—Directorate General of Foreign Trade of the Ministry of Trade.
Israel—The Diamond Controller.
Ivory Coast—Ministry of Mines and Energy.
Japan—Ministry of Economy, Trade and Industry.
Republic of Korea—Ministry of Commerce, Industry and Energy.
Laos—Ministry of Finance.
Lebanon—Ministry of Economy and Trade.
Lesotho—Commissioner of Mines and Geology.
Liberia—Ministry of Lands, Mines and Energy.
Malaysia—Ministry of International Trade and Industry.
Mauritius—Ministry of Commerce.
Namibia—Ministry of Mines and Energy.
New Zealand—Ministry of Foreign Affairs and Trade.
Norway—The Norwegian Goldsmiths' Association.
Russia—Gokhran, Ministry of Finance.
Sierra Leone—Government Gold and Diamond Office.
Singapore—Singapore Customs.
South Africa—South African Diamond Board.
Sri Lanka—National Gem and Jewelry Authority.
Switzerland—State Secretariat for Economic Affairs.
Chinese Taipei—Bureau of Foreign Trade.
Tanzania—Commissioner for Minerals.
Thailand—Ministry of Commerce.
Togo—Ministry of Mines and Geology.
Turkey—Istanbul Gold Exchange.
Ukraine—State Gemological Centre of Ukraine.
United Arab Emirates—Dubai Metals and Commodities Center.
United States of America—Importing Authority—United States Bureau of Customs and Border Protection; Exporting Authority—Bureau of the Census.
Vietnam—Ministry of Trade.
Zimbabwe—Ministry of Mines and Mining Development.

This notice shall be published in the **Federal Register**.

Dated: August 11, 2008.

John D. Negroponte,

Deputy Secretary of State, Department of State.

[FR Doc. E8–20736 Filed 9–5–08; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Airport Improvement Program Grant Assurances; Proposed Modifications and Opportunity To Comment

AGENCY: Federal Aviation Administration (FAA), U.S. DOT.

ACTION: Notice of modification of Airport Improvement Program grant application requirements and of the opportunity to comment.

SUMMARY: The FAA proposes to modify the standard grant application requirements that are required of a sponsor of a nonprimary airport before receiving a grant under the Airport Improvement Program (AIP). The FAA is providing an opportunity for public comment on proposals to modify the grant application requirements.

Sponsors of nonprimary airports are now required to provide a variety of information when submitting an AIP grant application. This modification would require that a sponsor of a nonprimary airport submit a list of the aircraft (fixed wing and rotary wing) that are based on the airport.

DATES: Comments are invited. Comments must be submitted on or before October 8, 2008. Any necessary or appropriate revision to the application requirements resulting from the comments received will be adopted as of the date of a subsequent publication in the **Federal Register**.

ADDRESSES: Comments may be delivered or mailed to the FAA, Airports Financial Assistance Division, APP–500, Room 619, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Heibeck, Airports Planning and Programming Division, APP 2, Room 620, FAA, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–8775.

SUPPLEMENTARY INFORMATION: In order to be considered for AIP grant funds, a sponsor (the grant applicant) must meet certain requirements and provide certain information regarding the project for which grant funds are being sought. The Secretary must receive this information from a sponsor (applicant) seeking financial assistance for airport planning, airport development, noise compatibility planning or noise mitigation under Title 49, U.S.C., as amended. Decisions to award discretionary grants are made on the basis of a number of factors. Nonprimary airports that have not provided verifiable data regarding the number of aircraft that are based at the airport hinder FAA from determining whether a project at that airport is justified. Therefore, if a nonprimary airport has not provided the verifiable based aircraft information, FAA will consider the failure to provide the information as a factor when considering a request from that airport for discretionary funding.

Discussion of Modifications

FAA prescribes the information that must be contained in a grant application. For nonprimary airport grant applications, FAA has determined that accurate information on based aircraft is an important element of justification for many proposed AIP projects at nonprimary airports. In addition, based aircraft data supports the airport's importance in the biennial Report to Congress—the National Plan of Integrated Airport Systems (NPIAS) and in the Airport Master Record (the Form 5010). A based aircraft is an operational aircraft that is registered in the FAA Aircraft Registry that is at the airport the majority of the year. Registered aircraft are defined in Chapter 14 Code of Federal Regulations Part 47. An operational aircraft is an aircraft that is in a condition for safe operation.

FAA may require a sponsor for a nonprimary airport to include a list of the based aircraft at the airport, including the ''N-number'' for each aircraft when submitting a grant application or may require the sponsor to update the list of based aircraft submitted with the most recent Form 5010 inspection.

The FAA manages the AIP in accordance with statutory direction and agency policies and criteria. Decisions

to award discretionary grants are made on the basis of a number of factors, including project evaluation under the National Priority System and the current operations and number of aircraft that are based at an airport. Nonprimary airports that have not provided verifiable data on the number of based aircraft at the airport deprive FAA of a tool for reviewing discretionary requests. Therefore, if a nonprimary airport has not provided a list of based aircraft at the airport, including ''N-number'', FAA will consider the failure to provide the information as a factor when considering a request from the airport for discretionary funding.

Issued in Washington, DC on August 27, 2008.

Wayne Heibeck,

Deputy Director, Office of Airport Planning and Programming.

[FR Doc. E8–20459 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss transport airplane and engine (TAE) issues.

DATES: The meeting is scheduled for Wednesday, October 1, 2008, starting at 9 a.m. Pacific Daylight Time. Arrange for oral presentations by September 16, 2008.

ADDRESSES: FAA–Northwest Mountain Region Office, Transport Standards Staff conference room, 1601 Lind Ave. SW., Renton, WA 98507.

FOR FURTHER INFORMATION CONTACT: Ralen Gao, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–3168, FAX (202) 267–5075, or e-mail at *ralen.gao@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to be held October 1, 2008.

The agenda for the meeting is as follows:

- Opening Remarks, Review Agenda and Minutes.
- FAA Report.
- Excom Report.
- Transport Canada Report.
- Airplane-level Safety Analysis Working Group Report.
- Task 4 Status.
- Propeller Harmonization Working Group (HWG) Report.
- Ice protection HWG Report.
- Airworthiness Assurance HWG Report.
- Avionics HWG Report.
- Halon Replacement as Fire Extinguishing Agent.
- Any Other Business.
- Action Item Review.

Attendance is open to the public, but will be limited to the availability of meeting room space. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than September 16, 2008. Entrance to the FAA facility will require presentation of a valid passport or state-issued (US) identification (e.g, driver's license). Please plan on arriving at least 20 minutes in advance of meeting to facilitate entrance screening.

For persons participating by telephone, the call-in number is (202) 366–3920; the pass code is ''2816.'' To insure that sufficient telephone lines are available, please notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section of your intent to participate by telephone by September 16, 2008. Anyone calling from outside the Seattle, WA metropolitan area will be responsible for paying long-distance charges.

The public must make arrangements by September 16, 2008, to present oral statements at the meeting. Written statements may be presented to the ARAC at any time by providing 25 copies to the person listed in the **FOR FURTHER INFORMATION CONTACT** section or by providing copies at the meeting. Copies of the documents to be presented to ARAC for decision by the FAA may be made available by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

If you need assistance or require a reasonable accommodation for the meeting or meeting documents, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting.

Issued in Washington, DC on September 3, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E8–20747 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement and Environmental Impact Report: San Francisco, CA

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent (NOI) to prepare a joint Environmental Impact Statement/Environmental Impact Report (EIS/EIR).

SUMMARY: The FHWA, on behalf of the California Department of Transportation (Caltrans), and The San Francisco County Transportation Authority (Authority), is issuing this notice to advise the public that an Environmental Impact Statement/Environmental Impact Report (EIS/EIR) will be prepared for the proposed Yerba Buena Island (YBI) Ramps Improvement Project on Interstate 80 (I–80) in San Francisco County, California.

FOR FURTHER INFORMATION CONTACT: Eric Cordoba, San Francisco County Transportation Authority, 100 Van Ness Avenue, 26th Floor, San Francisco, CA 94102, Telephone (415) 955–2904 or Melanie Brent, Caltrans District 4 Office of Environmental Analysis, 111 Grand Avenue, Oakland, CA 94623, Telephone (510) 286–5231.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, National Environmental Policy Act (NEPA) environmental responsibilities for highway projects pursuant to 23 U.S.C. 327. In cooperation with Caltrans, the Authority will prepare a joint EIS/EIR for the proposed YBI Ramps Improvement Project at Yerba Buena Island in the City and County of San Francisco, California. Caltrans is the lead agency under NEPA and the Authority is the lead agency under the California Environmental Quality Act (CEQA).

YBI is located in San Francisco Bay, between Oakland and San Francisco, and is accessible by vehicles only via the San Francisco-Oakland Bay Bridge (SFOBB), which is a critical link in the interstate network, providing access between San Francisco and the East Bay. The only access to Treasure Island, located north of YBI, and the only land access to the active U.S. Coast Guard facilities on the south side of YBI, is also from the SFOBB and the associated on- and off-ramps.

The proposed project would replace the existing westbound on- and off-

ramps located on the east side of YBI with new westbound on- and off-ramps that replicate the functional role of the current ramps and also address seismic, traffic safety requirements, and design standards. The feasibility of improving the geometric configuration of the current eastbound off-ramp on the eastern side of YBI to Hillcrest Road will also be included. The YBI Ramps Improvement Project is separate and independent of both the SFOBB East Span Seismic Safety Project currently under construction, and the Treasure Island and Yerba Buena Island (TI/YBI) Redevelopment Plan, which is currently undergoing its own environmental review process. The proposed new ramps would improve traffic and seismic safety of the ramps and provide connections between YBI and the transition structure of the new SFOBB. The proposed project is located between Post Mile (PM) 7.8 and 8.1 starting at the east portal of the YBI tunnel and ending before the SFOBB Transition Structure.

The purpose of the project is to address geometric and operational deficiencies of the existing on- and off-ramps, improve traffic operations to and from the SFOBB and improve traffic safety by increasing deceleration length for the eastbound and westbound off-ramps, and increasing merging distance for eastbound and westbound on-ramps. Preliminary alternatives under consideration for the EIS/EIR include:

(1) No Build Alternative, which assumes that the existing on- and off-ramps would remain in place and no further action or improvements would occur;

(2) Alternative 2B, which would include the removal of the existing westbound on- and off-ramps on the east side of YBI, construction of a westbound off-ramp to Macalla Court on the east side of YBI, construction of a westbound hook on-ramp from Macalla Court on the east side of YBI. The feasibility of incorporating improvements to the current eastbound off-ramp on the eastern side of YBI to Hillcrest Road will be studied; and,

(3) Alternative 4, which would include the removal of the existing westbound on- and off-ramps on the east side of YBI, the construction of westbound on-ramp from Hillcrest Road, the construction of westbound off-ramp from Macalla Court on the east side of YBI. The feasibility of incorporating improvements to the current eastbound off-ramp on the eastern side of YBI to Hillcrest Road will be studied.

Anticipated Federal approvals or permits include, U.S. Fish and Wildlife Service (USFWS) Section 7 Endangered Species Act, Consultation, Sections 401 and 404 of the Clean Water Act, Section 4(f) of the Transportation Act of 1966, Section 6(f) Land and Water Conservation Fund Act, Section 10 Army Corp of Engineers (ACOE), Section 9 Coast Guard, and determination of consistency with the Federal Coastal Zone Management Act by the San Francisco Bay Conservation and Development Commission.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, participating agencies (including federally recognized Tribal governments, if any), local agencies, and private organizations and citizens who have previously expressed or are known to have interest in this proposal. The NEPA environmental process for the proposed project began in June 2008. A public scoping meeting is scheduled to be held at the Port of San Francisco office, in the Bayside Conference Room located at Pier 1, The Embarcadero, San Francisco, CA 94111 on Wednesday, September 24, 2008 from 6:30 to 8 p.m.

In addition, at least one public hearing will be held after the publication of the Draft EIS/EIR. Public notice will be given of the time and place of the meeting and hearing (as applicable). The Draft EIS/EIR will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comment or questions concerning this proposed action and the EIS should be directed to Eric Cordoba, Project Manager for the Authority, with a copy of comment sent to Melanie Brent, Caltrans Office Chief. Written comments must be received no later than 5 p.m. on October 6, 2008 and should be sent to Eric Cordoba at the Authority, with a copy of the comment sent to Melanie Brent at Caltrans at the addresses listed 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: September 5, 2008.

Nancy E. Bobb,

Director, State Programs, Federal Highway Administration, Sacramento, California.

[FR Doc. E8–20698 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR Part 236, as detailed below.

[Docket Number FRA–2008–0094]

Applicant: Wheeling & Lake Erie Railway Company, Mr. Dan Reinsel, Signal & Communications Supervisor, 100 East First Street, Brewster, OH 44613.

The Wheeling & Lake Erie Railway Company seeks approval of the proposed discontinuance of the signal system governing movements over the Maumee River turn span bridge at MP 2.38, Toledo, Ohio.

The reason given for the proposed changes is that a damaged mechanical circuit coupler located on the east end of the turn span is no longer in production and attempts to secure a replacement have been unsuccessful. Replacement of the entire system would be of excessive cost given the amount of rail traffic across the bridge.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

All communications concerning this proceeding should be identified by Docket Number FRA–2008–0094 and may be submitted by one of the following methods:

- *Web site:* *http://www.regulations.gov.* Follow the instructions for submitting comments on the DOT electronic site;
- *Fax:* 202–493–2251;
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200

New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; or

• *Hand Delivery:* Room W12–140 of the U.S. Department of Transportation West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://www.regulations.gov.*

Issued in Washington, DC on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20758 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Burlington Junction Railway

[Waiver Petition Docket Number FRA–2008–0012]

The Burlington Junction Railway (BJRY) of Burlington, Iowa, has petitioned for a permanent waiver of compliance for one diesel-electric locomotive built in March 1951, model SW–8 and numbered BJRY 900, from the requirements of the Railroad Safety Glazing Standards, Title 49 CFR Part 223, which require certified glazing in all windows. The locomotive is presently located in Montgomery, Illinois. The railroad indicates that the locomotive is used to switch an industrial park next to the City of Rochelle, Illinois, over an approximately 3.0-mile long track surrounded by warehouses and underdeveloped rural agriculture fields. The top speed of operations is 10 mph.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2008–0012) and may be submitted by any of the following methods:

• *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC, on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20729 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Squaw Creek Southern Railroad, Inc.

[Waiver Petition Docket Number FRA–2008–0020]

The Squaw Creek Southern Railroad, Inc. of Boonville, Indiana, has petitioned for a permanent waiver of compliance for one SD–38–2 model locomotive (numbered RRC–20) built by the Electromotive Division of General Motors from the requirements of the *Railroad Safety Glazing Standards,* 49 CFR Part 223, which requires certified glazing in all windows. The railroad indicates that it operates between Yankeetown and Lynnville, Indiana, with trackage rights over approximately 21 miles of Norfolk Southern (NS) systems track owned, operated and maintained by NS. The railroad implies economic hardship for the replacement of existing glazing with FRA certified glazing per requirements of 49 CFR Part 223.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires

an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2008–0020) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC, on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20727 Filed 9–8–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Informational Filing

In accordance with § 236.913 of Title 49 of the Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received an informational filing from the Norfolk Southern Railway (NS) to permit field testing of the railroad's processor-based train control system. The informational filing is described below, including the requisite docket number where the informational filing and any related information may be found. The document is also available for public inspection; however, FRA is not accepting public comments.

Norfolk Southern Railway

[Docket Number FRA–2008–0083]

NS has submitted an informational filing to FRA to permit field testing of the railroad's processor-based train control system identified as Optimized Train Control (OTC) Positive Train Control (PTC) System. The informational filing addresses the requirements under 49 CFR 236.913(j)(1).

Specifically, the informational filing contains a description of the NS OTC PTC product and an operational concepts document pursuant to 49 CFR 236.913(j)(1). The NS OTC PTC system is designed to assist train crews in situational awareness, prevent authority limit and over-speed violations, provide open switch protection in non-signaled Track Warrant Control territory, and to prevent equipped trains from entering the limits without authorization of on-track authority granted to employees. NS desires to commence field testing on or after September 1, 2008, or as soon as practicable thereafter, contingent upon FRA's acceptance and approval of their informational filing.

Interested parties are invited to review the informational filing and associated documents at the DOT Docket Management facility during regular business hours (9 a.m.–5 p.m.) at 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590. All documents in the public docket are also available for inspection and copying on the Internet at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications received into any of our dockets by name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20757 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Austin & Texas Central Railroad

[Waiver Petition Docket Number FRA–2008–0066]

The Austin & Texas Central Railroad (ATCX) of Austin, Texas, has petitioned for an extension of an existing safety glazing waiver (RSGM–97–02) of compliance from Title 49 CFR Part 223 to increase running track speed for four sleeper/lounge passenger cars operated by ATCX in excursion service. These cars are two sleeper lounge passenger cars NKP–151 and ATSF 1343, and two Pullman Coach Cars ATCX 107 and ATCX 325.

ATCX intends to use the cars in passenger excursion service at speeds not to exceed 25 miles per hour (mph) over 154 miles of track owned by the city of Austin, Texas, between Cedar Park, TX, and Burnette, TX. ATCX operates one train daily on weekends from March to December, with occasional weekday trains. The original waiver specified that the maximum track speed shall not exceed 20 mph under condition #7. The following are reasons for the request to increase the track speed to 25 mph:

- The authority to occupy the main track is now in the form of Track Warrant Control for the majority of the line and yard limits in a few limited areas.
- Track warrants are issued by controllers in a centralized dispatching center and apply to all rail line traffic including passenger, commuter, freight, and Hyrail and Maintenance of Way Operations.
- Maximum authorized speed is now 25 mph as per ATCX Timetable 2.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2008–0066) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC, on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20725 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for temporary waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the parties seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Norfolk Southern Railway

[Waiver Petition Docket Number FRA–2008–0083]

The Norfolk Southern Railway (NS) has submitted a temporary waiver petition to support field testing of its processor-based train control system identified as NS Optimized Train Control (OTC) system, pursuant to 49 CFR 211.7 and 211.51.

An informational filing, as required under 49 CFR Part 236, Subpart H, has also been prepared and submitted in conjunction with this waiver petition, and can be found in the same docket as this waiver petition.

The NS OTC Positive Train Control (PTC) system is designed to assist train crews in situational awareness, prevent authority limit and over-speed violations, provide open switch protection in non-signaled Track Warrant Control (TWC) territory, and to prevent equipped trains from entering the limits, without authorization, of on-track authority granted to employees.

NS desires to commence field testing of the NS OTC PTC system on or after September 1, 2008, or as soon as practicable thereafter, contingent upon FRA's acceptance and approval of the informational filing and waiver petition. NS intends to test and develop the NS OTC PTC system on it's Charleston district between milepost SC7.0 (Charleston Station) and milepost SC128.9 (Andrews Yard Station, as well as on it's Columbia district between milepost R0.0 Charlotte Junction station) and milepost R108.5 (Andrews Yard station). During this initial test phase, NS does not intend to activate the NS OTC PTC system's locomotive enforcement functionality.

NS is seeking regulatory relief for development testing and demonstration purposes only. Specifically, NS is requesting regulatory relief from the following FRA requirements:

49 CFR 216.13 (Special Notice for Repairs—Locomotive);

49 CFR 217.9 (Program of Operational Tests and Inspections—Recordkeeping);

49 CFR 217.11 (Program of Instruction on Operating Rules—Recordkeeping, Electronic Recordkeeping);

49 CFR Part 218 [Subpart D] (Prohibition against tampering with safety devices);

49 CFR 229.7 (Prohibited Acts);

49 CFR 229.135 (Event Recorders);

49 CFR 233.9 (Annual Reports);

49 CFR 235.5 (Changes Requiring Filing of Application);

49 CFR 240.127 (Criteria for Examining Skill Performance); and

49 CFR 240.129 (Criteria for Monitoring Operational Performance of Certified Engineers).

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. All communications concerning these proceedings should identify the appropriate docket number (Docket Number FRA–2008–0083) and may be submitted by one of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received within 30 days of the date of this notice will be considered by FRA before final action being taken. Comments received after this period will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the DOT Docket Management Facility, 1200 New Jersey Avenue, SE., Room W12–140, in Washington DC. All documents in the public docket are also available for inspection and copying on the internet at *http://www.regulations.gov.*

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by name of the individual submitting the

comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on September 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–20708 Filed 9–5–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Advisory Committee on the Auditing Profession

AGENCY: Office of the Undersecretary for Domestic Finance, Treasury.

ACTION: Notice of meeting.

SUMMARY: The Department of the Treasury's Advisory Committee on the Auditing Profession will convene a telephone conference meeting on Friday, September 26, 2008, beginning at 10 a.m. Eastern Time. Members of the public may take part in the meeting by listening to the Webcast accessible on the Department's Web site at *http://www.treas.gov/offices/domestic-finance/acap/index.shtml* or by calling telephone number (866) 780–1271 and using access code number 62607180. Persons needing special accommodations to take part because of a disability should notify the contact person listed below.

DATES: The meeting will be held on Friday, September 26, 2008, at 10 a.m. Eastern Time.

ADDRESSES: The public is invited to submit written statements with the Advisory Committee by any of the following methods:

Electronic Statements

- Use the Department's Internet submission form (*http://www.treas.gov/offices/domestic-finance/acap/comments*); or

Paper Statements

- Send paper statements in triplicate to Advisory Committee on the Auditing Profession, Office of Financial Institutions Policy, Room 1418, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

In general, the Department will post all statements on its Web site (*http://www.treas.gov/offices/domestic-finance/acap/comments*) without change, including any business or personal information provided such as names, addresses, e-mail addresses, or telephone numbers. The Department will also make such statements available for public inspection and copying in the Department's Library, Room 1428, Main Department Building, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect statements by telephoning (202) 622–0990. All statements, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Kristen E. Jaconi, Senior Policy Advisor to the Under Secretary for Domestic Finance, Department of the Treasury, Main Department Building, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, at (202) 927–6618.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and the regulations thereunder, David G. Nason, Designated Federal Officer of the Advisory Committee, has ordered publication of this notice that the Advisory Committee will convene a telephone conference meeting on Friday, September 26, 2008, beginning at 10 a.m. Eastern Time. Members of the public may take part in the meeting by listening to the Webcast accessible on the Department's Web site at *http://www.treas.gov/offices/domestic-finance/acap/index.shtml* or by calling telephone number (866) 780–1271 and using access code number 62607180. The agenda for this meeting includes adoption of the Advisory Committee's final report to the Department.

Dated: September 2, 2008.

Taiya Smith,

Executive Secretary.

[FR Doc. E8–20705 Filed 9–5–08; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OCC is soliciting comment concerning its information collection titled, ''Fair Housing Home Loan Data System Regulation—12 CFR 27.'' The OCC is also giving notice that it has submitted the collection to OMB for review.

DATES: You should submit your comments by October 8, 2008.

ADDRESSES: You should direct all written comments to: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mailstop 1–5, Attention: 1557–0159, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–4448, or by electronic mail to *regs.comments@occ.treas.gov*. You can inspect and photocopy the comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–5043. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to OCC Desk Officer, 1557–0159, by mail to U.S. Office of Management and Budget, 725 17th Street, NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information from Mary H. Gottlieb, OCC Clearance Officer, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to revise the following information collection:

Title: Fair Housing Home Loan Data System Regulation—12 CFR Part 27.

OMB Control No.: 1557–0159.

Description: The Fair Housing Act (42 U.S.C. 3605) prohibits discrimination in the financing of housing on the basis of race, color, religion, sex, or national origin. The Equal Credit Opportunity Act (15 U.S.C. 1691 *et seq.*) prohibits discrimination in any aspect of a credit transaction on the basis of race, color, religion, national origin, sex, marital status, age, receipt of income from public assistance, or exercise of any right under the Consumer Credit Protection Act. The OCC is responsible for ensuring that national banks comply with those laws. This information collection is needed to promote national bank compliance and for OCC to fulfill its statutory responsibilities.

The information collection requirements in 12 CFR part 27 are as follows:

- Section 27.3(a) requires a national bank that is required to collect data on home loans under 12 CFR part 203 to present the data on Federal Reserve Form FR HMDA–LAR,[1] or in automated format in accordance with the HMDA–LAR instructions, and to include one additional item (the reason for denial) on the HMDA–LAR. Section 27.3(a) also lists exceptions to the HMDA–LAR recordkeeping requirements.
- Section 27.3(b) lists the information banks should obtain from an applicant as part of a home loan application, and states information that a bank must disclose to an applicant.
- Section 27.3(c) sets forth additional information required to be kept in the loan file.
- Section 27.4 states that the OCC may require a national bank to maintain a Fair Housing Inquiry/Application Log found in Appendix III to part 27 if there is reason to believe that the bank is engaging in discriminatory practices or if analysis of the data compiled by the bank under the Home Mortgage Disclosure Act (12 U.S.C. 2801 *et seq.*) and 12 CFR part 203 indicates a pattern of significant variation in the number of home loans between census tracts with similar incomes and home ownership levels differentiated only by race or national origin.
- Section 27.5 requires a national bank to maintain the information required by § 27.3 for 25 months after the bank notifies the applicant of action taken on an application, or after withdrawal of an application.
- Section 27.7 requires a national bank to submit the information required by §§ 27.3(a) and 27.4 to the OCC upon its request, prior to a scheduled examination using the Monthly Home Loan Activity Format form in Appendix I to part 27 and the Home Loan Data Form in Appendix IV to part 27.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1,712.

Estimated Total Annual Responses: 2,871.

Estimated Frequency of Response: On occasion.

Estimated Time Per Respondent: 2.68 hours.

Estimated Total Annual Burden: 4,595.84 hours.

A 60-day **Federal Register** notice was issued on June 24, 2008. 73 FR 35722. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: September 2, 2008.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. E8–20682 Filed 9–5–08; 8:45 am]

BILLING CODE 4810–33–P

[1] Loan Application Register, *http://www.ffiec.gov/hmda/doc/hmdalar2007.doc.*

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel—Notice of Closed Meeting

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of closed meeting of Art Advisory Panel.

SUMMARY: Closed meeting of the Art Advisory Panel will be held in Washington, DC.

DATES: The meeting will be held October 1 and 2, 2008.

ADDRESSES: The closed meeting of the Art Advisory Panel will be held on October 1 and 2, 2008, in Room 4136 beginning at 9:30 a.m., Franklin Court Building, 1099 14th Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Karen Carolan, C:AP:ART, 1099 14th Street, NW., Washington, DC 20005. Telephone (202) 435–5609 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App., that a closed meeting of the Art Advisory Panel will be held on October 1 and 2, 2008, in Room 4136 beginning at 9:30 a.m., Franklin Court Building, 1099 14th Street, NW., Washington, DC 20005.

The agenda will consist of the review and evaluation of the acceptability of fair market value appraisals of works of art involved in Federal income, estate, or gift tax returns. This will involve the discussion of material in individual tax returns made confidential by the provisions of 26 U.S.C. 6103.

A determination as required by section 10(d) of the Federal Advisory Committee Act has been made that this meeting is concerned with matters listed in 5 U.S.C. section 552b(c)(3), (4), (6), and (7), and that the meeting will not be open to the public.

Sarah Hall Ingram,

Chief, Appeals.

[FR Doc. E8–20772 Filed 9–5–08; 8:45 am]

BILLING CODE 4830–01–P

Federal Register

Monday,
September 8, 2008

Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 226

Endangered and Threatened Wildlife and Plants: Proposed Rulemaking To Designate Critical Habitat for the Threatened Southern Distinct Population Segment of North American Green Sturgeon; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 226

[Docket No. 080730953–81003–01]

RIN 0648–AX04

Endangered and Threatened Wildlife and Plants: Proposed Rulemaking To Designate Critical Habitat for the Threatened Southern Distinct Population Segment of North American Green Sturgeon

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

ACTION: Proposed rule; request for comments.

SUMMARY: We, the National Marine Fisheries Service (NMFS), propose to designate critical habitat for the threatened Southern distinct population segment of North American green sturgeon (Southern DPS of green sturgeon) pursuant to section 4 of the Endangered Species Act (ESA). Specific areas proposed for designation include: coastal U.S. marine waters within 110 meters (m) depth from Monterey Bay, California (including Monterey Bay), north to Cape Flattery, Washington, including the Strait of Juan de Fuca, Washington, to its United States boundary; the Sacramento River, lower Feather River, and lower Yuba River in California; the Sacramento-San Joaquin Delta and Suisun, San Pablo, and San Francisco bays in California; the lower Columbia River estuary; and certain coastal bays and estuaries in California (Humboldt Bay), Oregon (Coos Bay, Winchester Bay, and Yaquina Bay), and Washington (Willapa Bay and Grays Harbor). The areas proposed for designation comprise approximately 325 miles (524 km) of freshwater river habitat, 1,058 square miles (2,739 sq km) of estuarine habitat, 11,927 square miles (30,890 sq km) of marine habitat, and 136 square miles (352 sq km) of habitat within the Yolo and Sutter bypasses (Sacramento River, CA).

We propose to exclude the following areas from designation because the benefits of exclusion outweigh the benefits of inclusion and exclusion will not result in the extinction of the species: coastal U.S. marine waters within 110 m depth from the California/Mexico border north to Monterey Bay, CA, and from the Alaska/Canada border northwest to the Bering Strait; and certain coastal bays and estuaries in California (Tomales Bay, Elkhorn Slough, Noyo Harbor, and the estuaries to the head of the tide in the Eel and Klamath/Trinity rivers), Oregon (Tillamook Bay and the estuaries to the head of the tide in the Rogue, Siuslaw, and Alsea rivers), and Washington (Puget Sound). The areas excluded from the proposed designation comprise approximately 1,057 square miles (2,738 sq km) of estuarine habitat and 396,917 square miles (1,028,015 sq km) of marine habitat.

We acknowledge that there may be costs incurred by those planning to undertake activities in certain areas, in particular Coo Bay, OR, or other areas along the lower Columbia River estuary, as a result of this proposed critical habitat designation for the Southern DPS of green sturgeon that were not captured in our draft economic report. These activities include, but are not limited to, liquefied natural gas (LNG) projects, hydropower activities, and alternative energy projects. We solicit comment on what these additional costs might be and will consider any additional information received in developing our final determination to designate or exclude areas from critical habitat for the Southern DPS of green sturgeon.

DATES: Comments on this proposed rule to designate critical habitat must be received by no later than 5 p.m. Pacific Standard Time on November 7, 2008. A public hearing will be held promptly if any person so requests by October 23, 2008. Notice of the date, location, and time of any such hearing will be published in the **Federal Register** not less than 15 days before the hearing is held.

ADDRESSES: You may submit comments on the proposed rule, identified by RIN 0648–AX04, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 1–562–980–4027, Attention: Melissa Neuman.
- *Mail:* Submit written information to Chief, Protected Resources Division, Southwest Region, National Marine Fisheries Service, 650 Capitol Mall, Sacramento, CA 95814–4706.

Instructions: 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 (for example, name, address, etc.) 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 (please 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 PDF file formats only.

Reference materials regarding this determination can be obtained via the Internet at: *http://www.nmfs.noaa.gov* or by submitting a request to the Assistant Regional Administrator, Protected Resources Division, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: Melissa Neuman, NMFS, Southwest Region (562) 980–4115 or Lisa Manning, NMFS, Office of Protected Resources (301) 713–1401.

SUPPLEMENTARY INFORMATION:

Background

We determined that the Southern DPS of green sturgeon is likely to become endangered in the foreseeable future throughout all or a significant portion of its range and listed the species as threatened under the Endangered Species Act (ESA) on April 7, 2006 (71 FR 17757).

Section 4(b)(2) of the ESA requires us to designate critical habitat for threatened and endangered species ''on the basis of the best scientific data available and after taking into consideration the economic impact, impact on national security, and any other relevant impact, of specifying any particular area as critical habitat.'' This section grants the Secretary [of Commerce] discretion to exclude any area from critical habitat if he determines ''the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat.'' The Secretary may not exclude an area if it ''will result in the extinction of the species.''

The ESA defines critical habitat under Section 3(5)(A) as:

> ''(i) the specific areas within the geographical area occupied by the species, at the time it is listed * * *, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and
>
> (ii) specific areas outside the geographical area occupied by the species at the time it is listed * * * upon a determination by the Secretary that such areas are essential for the conservation of the species.''

Once critical habitat is designated, section 7 of the ESA requires Federal

agencies to ensure they do not fund, authorize, or carry out any actions that will destroy or adversely modify that habitat. This requirement is in addition to the ESA section 7 requirement that Federal agencies ensure their actions do not jeopardize the continued existence of listed species.

When the final rule to list the Southern DPS of green sturgeon was published on April 7, 2006, we solicited from the public information that would inform the decision-making process for designating critical habitat for the species. Specifically, we requested information regarding: (1) Green sturgeon spawning habitat within the range of the Southern DPS that was present in the past, but may have been lost over time; (2) biological or other relevant data concerning any threats to the Southern DPS of green sturgeon; (3) quantitative evaluations describing the quality and extent of freshwater and marine habitats (occupied currently or occupied in the past, but no longer occupied) for juvenile and adult green sturgeon as well as information on areas that may qualify as critical habitat in California for the Southern DPS; (4) activities that could be affected by an ESA critical habitat designation; and (5) the economic costs and benefits of additional requirements of management measures likely to result from the designation. No substantive additional comments, beyond those that had been received during prior solicitations for information, were received.

The timeline for completing the proposed critical habitat designation described in this **Federal Register** document was established pursuant to a settlement agreement. On April 17, 2007, the Center for Biological Diversity (CBD) filed a 60-day notice of intent to sue the Secretary of Commerce and NMFS for failing to designate critical habitat and establish protective regulations for the Southern DPS of green sturgeon, as required by the ESA. Pursuant to the settlement agreement reached between the parties, we agreed to make a determination on a proposed critical habitat designation for the Southern DPS of green sturgeon by April 30, 2008, and a final designation by April 30, 2009, which were later extended to September 2, 2008 and June 30, 2009, respectively.

In developing this proposed rule, we evaluated the best available information regarding green sturgeon distribution and habitat requirements, as well as threats to the species. In the Final Rule to list the Southern DPS as threatened under the ESA (71 FR 17757; April 7, 2006), we identified seven extinction risk factors, including: (1) Concentration of spawning into one spawning river, increasing the risk of catastrophic extinction; (2) loss of spawning habitat in the upper Sacramento and Feather rivers due to migration barriers; (3) a general lack of population data, but suspected small population size; (4) entrainment by water project operations; (5) potentially limiting or lethal water temperatures; (6) commercial and recreational fisheries harvest; and (7) toxins and exotic species. This document describes the proposed critical habitat designation, including supporting information on green sturgeon biology, distribution, and habitat use, and the methods used to develop the proposed designation.

Green Sturgeon Natural History

In the following sections, we describe the natural history of green sturgeon as it relates to the habitat needs of this species. The green sturgeon is an anadromous fish species that is long-lived and the most marine oriented sturgeon species in the family Acipenseridae. The North American form of green sturgeon (*Acipenser medirostris;* hereafter, ''green sturgeon'') is related to the Asian form (*A. mikadoi,* also called Sakhalin sturgeon), but is most likely a different species (Artyukhin *et al.*, 2007). Green sturgeon is one of two sturgeon species occurring on the U.S. west coast, the other being white sturgeon (*Acipenser transmontanus*). Adults can reach up to 270 cm in total length (TL) and 175 kg in weight (Moyle, 2002); however, adults greater than 2 m TL and 90 kg in weight are not common (Skinner, 1972). Females are larger and older (approximately 162 cm TL and 16–20 years of age) than males (approximately 152 cm TL and 14–16 years of age) upon reaching reproductive maturity (Van Eenennaam *et al.*, 2006). Maximum ages most likely range from 60 to 70 years or older (Emmett *et al.*, 1991). Until recently, few studies have focused on green sturgeon due to its low abundance and low commercial value compared to white sturgeon.

Green sturgeon range from the Bering Sea, Alaska, to Enseñada, Mexico. A few green sturgeon have been observed off the southern California coast, including fish less than 100 cm TL (Fitch and Lavenberg, 1971, cited in Moyle *et al.*, 1995; Fitch and Schultz, 1978, cited in Moyle *et al.*, 1995). Green sturgeon abundance increases north of Point Conception, CA (Moyle *et al.*, 1995). Green sturgeon occupy freshwater rivers from the Sacramento River up through British Columbia (Moyle, 2002), but spawning has been confirmed in only three rivers, the Rogue River in Oregon and the Klamath and Sacramento rivers in California. Based on genetic analyses and spawning site fidelity (Adams *et al.*, 2002; Israel *et al.*, 2004), NMFS has determined green sturgeon are comprised of at least two distinct population segments (DPSs): (1) A Northern DPS consisting of populations originating from coastal watersheds northward of and including the Eel River (*i.e.*, the Klamath and Rogue rivers) (''Northern DPS''); and (2) a southern DPS consisting of populations originating from coastal watersheds south of the Eel River, with the only known spawning population in the Sacramento River (''Southern DPS''). The Northern DPS and Southern DPS are distinguished based on genetic data and spawning locations, but their distributions outside of natal waters generally overlap with one another (Chadwick, 1959; Miller, 1972; CDFG, 2002; Israel *et al.*, 2004; Moser and Lindley, 2007; Erickson and Hightower, 2007; Lindley *et al.*, 2008.). Both Northern DPS and Southern DPS green sturgeon occupy coastal estuaries and coastal marine waters from southern California to Alaska, including Humboldt Bay, the lower Columbia river estuary, Willapa Bay, Grays Harbor, and coastal waters between Vancouver Island, BC, and southeast Alaska (Israel *et al.*, 2004; Moser and Lindley, 2007; Lindley *et al.*, 2008). Thus, green sturgeon observed in coastal bays, estuaries, and coastal marine waters outside of natal rivers may belong to either DPS. However, the Northern DPS of green sturgeon is not classified as a listed species under the ESA. Tagging or genetics data are needed to determine to which DPS an individual fish belongs. The distribution of green sturgeon, and specifically of the Southern DPS, is described in detail under the section titled ''Geographical Areas Occupied by the Species and Specific Areas within the Geographical Areas Occupied.''

Spawning

Spawning frequency is not well known, but the best information suggests adult green sturgeon spawn every 2–4 years (Lindley and Moser, NMFS, 2004, pers. comm., cited in 70 FR 17386, April 6, 2005; Erickson and Webb, 2007). Beginning in late February, adult green sturgeon migrate from the ocean into fresh water to begin their spawning migrations (Moyle *et al.*, 1995). Spawning occurs from March to July, with peak activity from mid-April to mid-June (Emmett *et al.*, 1991). Spawning populations in North America have been confirmed in the Rogue (Erickson *et al.*, 2002; Farr and

Kern, 2005), Klamath, and Sacramento Rivers (Moyle *et al.*, 1992; CDFG, 2002). Klamath and Rogue River populations appear to spawn within 100 miles (161 km) of the ocean, whereas spawning on the mainstem Sacramento River has been documented over 240 miles (391 km) upstream, both downstream and upstream of Red Bluff Diversion Dam (RBDD) (Brown, 2007). Spawning most likely occurs in fast, deep water (> 3 m deep) over substrates ranging from clean sand to bedrock, with preferences for cobble substrates (Emmett *et al.*, 1991; Moyle *et al.*, 1995). Green sturgeon females produce 59,000 to 242,000 eggs, with fecundity increasing with fish length and age (Van Eenennaam *et al.*, 2006). Green sturgeon eggs are the largest of any sturgeon species, ranging from 4.04 to 4.66 mm in diameter, and have a thin chorionic layer (Van Eenennaam *et al.*, 2001; Van Eenennaam *et al.*, 2006). Eggs are broadcast spawned and likely adhere to substrates or settle into crevices of river bedrock or under gravel (Deng, 2000; Van Eenennaam *et al.*, 2001; Deng *et al.*, 2002). Van Eenennaam *et al.* (2001) reported that green sturgeon eggs have weak adhesiveness, but have since retracted that statement, noting instead that green sturgeon eggs are quite adhesive within a few minutes after release from the female (Van Eenennaam, UC Davis, 2008, pers. comm.). Optimum flow and temperature requirements for spawning and incubation are unclear, but spawning success in most sturgeons is related to these factors (Detlaff *et al.*, 1993). Average monthly water flow during the spawning season (March–July) ranged from 209–1,252 m^3/s in the Sacramento River over a 10-year period from 1996–2006 (*http://waterdata.usgs.gov*) and from 31–260 m^3/s in the Rogue River over a 4-year period from 2001–2004 (Erickson and Webb, 2007). Spawning may be triggered by small increases in water flow (Schaffter, 1997; Brown, 2007). Adult sturgeon occur in the Sacramento River when temperatures are between 8–14 °C (Moyle, 2002). In laboratory studies, the optimal thermal range for green sturgeon development was from 11 to 17–18 °C, and temperatures ≥ 23 °C were lethal to embryos (Van Eenennaam *et al.*, 2005).

Development of Early Life Stages

Green sturgeon embryos have poor swimming ability and exhibit a strong drive to remain in contact with structure, preferring cover and dark habitats to open bottom and illuminated habitats in laboratory experiments (Kynard *et al.*, 2005). In these experiments, early embryos made no effort to swim, suggesting embryos remain in spawning areas to develop (Kynard *et al.*, 2005). Newly emerged green sturgeon larvae in the laboratory hatched 144–216 hours, or 6–9 days, after fertilization (incubation temperatures ranged from 15–15.7 °C) and ranged from 12.6–15 mm in length (Van Eenennaam *et al.*, 2001; Deng *et al.*, 2002). Unlike other acipenserids, newly hatched larvae did not swim up toward the water surface within the first 5 days post hatch (dph), but remained in clumps near the bottom. By 5–6 dph, larvae exhibited nocturnal behavior, remaining clumped near the bottom during the day and actively swimming at night (Van Eenennaam *et al.*, 2001; Deng *et al.*, 2002). Upon onset of feeding at 10 dph (23.0–25.2 mm length) (Deng *et al.*, 2002), larvae are believed to initiate downstream migration from spawning areas, staying close to the bottom and periodically interrupting downstream movement with upstream foraging bouts (Kynard *et al.*, 2005).

Little is known about larval rearing habitat and requirements. Temperatures of 15 °C are believed to be optimal for larval growth, whereas temperatures below 11 °C or above 19 °C may be detrimental for growth (Cech *et al.*, 2000, cited in COSEWIC, 2004). Substrate may also affect growth and foraging behavior. Larvae reared on flat-surfaced substrates (slate-rock and glass) had higher specific growth rates than larvae reared on cobble or sand, most likely due to lower foraging effectiveness and greater activity levels in cobble and sand substrates (Nguyen and Crocker, 2007). Larvae complete metamorphosis to the juvenile stage at 45 dph, when fish range from 62.5 to 94.4 mm in length (Deng *et al.*, 2002).

Juveniles continue to grow rapidly, reaching 300 mm in length in one year and over 600 mm within 2–3 years (based on Klamath River fish; Nakamoto *et al.*, 1995). Laboratory experiments indicate juveniles may occupy fresh to brackish water at any age, but are able to completely transition to salt water at around 1.5 years in age (about 533 dph; mean TL of 75.2 plus or minus 0.7 cm) (Allen and Cech, 2007). Early juveniles at 100 and 170 dph tolerated prolonged exposure to saltwater, but experienced decreased growth and activity levels and, in some cases, mortality for individuals at 100 dph (Allen and Cech, 2007). These results were consistent with the Nakamoto *et al.* (1995) study indicating that juveniles rear in fresh and estuarine waters before dispersing into salt water at about 1 to 4 years in age (about 300 to 750 mm in length). Early juveniles also exhibit nocturnal behavior in all activities and initiate directed downstream movement in the fall, most likely to migrate to wintering habitats (Kynard *et al.*, 2005). Juvenile green sturgeon prefer temperatures of 15–16 °C with an upper limit of 19 °C, beyond which swimming performance may decrease and cellular stress may occur (Mayfield and Cech, 2004; Allen *et al.*, 2006). Laboratory measurements of oxygen consumption by juveniles ranged from 61.78 plus or minus 4.65 mg O_2 hr^{-1} kg^{-1} to 76.06 plus or minus 7.63 mg O_2 hr^{-1} kg^{-1}, with a trend of increasing oxygen consumption with increasing body mass (Allen and Cech, 2006). Studies on juvenile feeding in San Pablo Bay, Suisun Bay, and the Sacramento-San Joaquin Delta identified prey items of shrimp (*Neomysis awatchensis, Crangon franciscorum*), amphipods (*Corophium* spp., *Photis californica*), isopods (*Synidotea laticauda*), clams (*Macoma* spp.), annelid worms, and unidentified crabs and fishes (Ganssle, 1966; Radtke, 1966).

Adults and Subadults

To distinguish among different life stages, we used the following definitions. Adults are sexually mature fish, subadults are sexually immature fish that have entered into coastal marine waters (usually at 3 years of age), and juveniles are fish that have not yet made their first entry into marine waters. Green sturgeon spend a large portion of their lives in coastal marine waters as subadults and adults between spawning episodes. Subadult male and female green sturgeon spend at least approximately 6 and 10 years, respectively, at sea before reaching reproductive maturity and returning to freshwater to spawn for the first time (Nakamoto *et al.*, 1995). Adult green sturgeon spend as many as 2–4 years at sea between spawning events (Lindley and Moser, NMFS, pers. comm., cited in 70 FR 17386, April 6, 2005; Erickson and Webb, 2007). The average length at maturity for green sturgeon is estimated to be 152 cm TL (14–16 years) for males and 162 cm TL (16–20 years) for females in the Klamath River (Van Eenennaam *et al.*, 2006), and 145 cm TL for males and 166 cm TL for females in the Rogue River (Erickson and Webb, 2007). The maximum size of subadults is approximately 167 cm TL (Erickson and Webb, 2007).

Adults typically begin their upstream spawning migration in the spring and either migrate downstream after spawning, or reside within the river over the summer. In the Klamath River, tagged adults exhibited four movement patterns: (1) Upstream spawning migration; (2) spring outmigration to the

ocean; (3) summer holding (June to November) in deep pools with eddy currents (for those that do not exhibit post-spawning spring outmigration); and (4) outmigration after summer holding (Benson *et al.*, 2007). Use of summer holding sites has also been observed in the Rogue River (Erickson *et al.*, 2002) and in the Sacramento River (R. Corwin, U.S. Bureau of Reclamation (USBR), 2008, pers. comm.). Deep holding pools greater than 5 m in depth are believed to be important for spawning as well as for summer holding (R. Corwin, USBR, and B. Poytress, USFWS, 2008, pers. comm). Winter outmigration from the Klamath and Rogue rivers was initiated when temperatures dropped to 10–12 °C or below 10 °C, and when discharge increased to greater than 100 m^3/s (Erickson *et al.*, 2002; Benson *et al.*, 2007). In the Sacramento River, tagged adult green sturgeon were present through November and December, before moving downstream with increased winter flows (M. Thomas, UC Davis, and R. Corwin, USBR, 2008, pers. comm.). Subadults may also migrate upstream into the natal rivers, but for unknown purposes. Adults and subadults also occupy the San Francisco, San Pablo, and Suisun bays and the Sacramento-San Joaquin Delta adjacent to the Sacramento River in the summer months (although some individuals that remain in the river until late fall/early winter migrate through the bays and Delta during their winter outmigration), during which time they are likely feeding and optimizing growth (Kelly *et al.*, 2007; Moser and Lindley, 2007).

Outside of their natal waters, adult and subadult green sturgeon inhabit coastal marine habitats from the Bering Sea to southern California, primarily occupying waters within 110 meters (m) depth (Erickson and Hightower, 2007). Tagged subadults and adults have been documented to make sustained coastal migrations of up to 100 km per day (S. Lindley and M. Moser, NMFS, pers. comm., cited in BRT, 2005), but may also reside in aggregation/feeding areas in coastal marine waters for several days at a time (S. Lindley and M. Moser, NMFS, 2008, pers. comm.). There is evidence that green sturgeon inhabit certain estuaries on the northern California, Oregon, and Washington coasts during the summer, and inhabit coastal marine waters along the central California coast and between Vancouver Island, British Columbia, and southeast Alaska over the winter (Lindley *et al.*, 2008). Green sturgeon likely inhabit these estuarine and marine waters to feed and to optimize growth (Moser and Lindley, 2007). Particularly large aggregations of green sturgeon occur in the Columbia River estuary and Washington estuaries and include green sturgeon from all known spawning populations (Moser and Lindley, 2007). Although adult and subadult green sturgeon occur in coastal marine waters as far north as the Bering Sea, green sturgeon have not been observed in freshwater rivers or coastal bays and estuaries in Alaska.

Within bays and estuaries, adults and subadults inhabit a wide range of environmental conditions. Adults and subadults in Willapa Bay and the San Francisco Bay Estuary occurred over the entire temperature and salinity range (11.9–21.9 °C; 8.8–32.1 ppt), experienced large fluctuations in temperature and salinity (up to 2 °C h^{-1} and 1 practical salinity unit (PSU) h^{-1}), and occupied a wide range of dissolved oxygen levels from 6.54 to 8.98 mg O_2/l (Kelly *et al.*, 2007; Moser and Lindley, 2007). Tagged adults and subadults in the San Francisco Bay Estuary occupied shallow depths during directional movements but stayed close to the bottom during non-directional movements, presumably because they were foraging (Kelly *et al.*, 2007). Similar to freshwater rivers, winter outmigration from Willapa Bay was initiated when water temperatures dropped below 10 °C (Moser and Lindley, 2007).

Adult and subadult green sturgeon in the Columbia River estuary, Willapa Bay, and Grays Harbor feed on crangonid shrimp, burrowing thalassinidean shrimp (primarily the burrowing ghost shrimp (*Neotrypaea californiensis*), but possibly other related species), amphipods, clams, juvenile Dungeness crab (*Cancer magister*), anchovies, sand lances (*Ammodytes hexapterus*), lingcod (*Ophiodon elongatus*), and other unidentified fishes (P. Foley, unpublished data cited in Moyle *et al.*, 1995; C. Tracy, minutes to USFWS meeting, cited in Moyle *et al.*, 1995; O. Langness, WDFW, pers. comm., cited in Moser and Lindley, 2007; Dumbauld *et al.*, 2008). Burrowing ghost shrimp made up about 50 percent of the stomach contents of green sturgeon sampled in 2003 (Dumbauld *et al.*, 2008). Subadults and adults feeding in bays and estuaries may be exposed to contaminants that may affect their growth and reproduction. Studies on white sturgeon in estuaries indicate that the bioaccumulation of pesticides and other contaminants adversely affects growth and reproductive development and may result in decreased reproductive success (Fairey *et al.*, 1997; Foster *et al.*, 2001a; Foster *et al.*, 2001b; Kruse and Scarnecchia, 2002; Feist *et al.*, 2005; Greenfield *et al.*, 2005). Green sturgeon are believed to experience similar risks from contaminants (70 FR 17386, April 6, 2005).

Methods and Criteria Used to Identify Critical Habitat

In the following sections, we describe the relevant definitions and requirements in the ESA and our implementing regulations and the key methods and criteria used to prepare this proposed critical habitat designation. In accordance with section 4(b)(2) of the ESA and our implementing regulations (50 CFR 424.12(a)), this proposed rule is based on the best scientific information available concerning the Southern DPS's present and historical range, habitat, and biology, as well as threats to its habitat. In preparing this rule, we reviewed and summarized current information on the green sturgeon, including recent biological surveys and reports, peer-reviewed literature, NMFS status reviews for green sturgeon (Moyle *et al.*, 1992; Adams *et al.*, 2002; BRT, 2005), and the proposed and final listing rules for the green sturgeon (70 FR 17386, April 6, 2005; 71 FR 17757, April 7, 2006).

To assist with the evaluation of critical habitat, we convened a critical habitat review team (CHRT) of nine Federal biologists from NMFS, the U.S. Fish and Wildlife Service (USFWS), and the USBR with experience in green sturgeon biology, consultations, and management, or experience in the critical habitat designation process. The CHRT used the best available scientific and commercial data and their best professional judgment to: (1) Verify the geographical area occupied by the Southern DPS at the time of listing; (2) identify the physical and biological features essential to the conservation of the species; (3) identify specific areas within the occupied area containing those essential physical and biological features; (4) verify whether the essential features within each specific area may need special management considerations or protection and identify activities that may affect these essential features; (5) evaluate the conservation value of each specific area; and (6) determine if any unoccupied areas are essential to the conservation of the Southern DPS. The CHRT's evaluation and conclusions are described in detail in the following sections.

Physical or Biological Features Essential for Conservation

Joint NMFS–USFWS regulations, at 50 CFR 424.12(b), state that in determining what areas are critical habitat, the agencies ''shall consider those physical and biological features that are essential to the conservation of a given species and that may require special management considerations or protection.'' Features to consider may include, but are not limited to: ''(1) Space for individual and population growth, and for normal behavior; (2) Food, water, air, light, minerals, or other nutritional or physiological requirements; (3) Cover or shelter; (4) Sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and generally; (5) Habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.'' The regulations also require the agencies to ''focus on the principal biological or physical constituent elements'' (hereafter referred to as ''Primary Constituent Elements'' or PCEs) within the specific areas considered for designation that are essential to conservation of the species, which ''may include, but are not limited to, the following: * * * spawning sites, feeding sites, seasonal wetland or dryland, water quality or quantity, * * * geological formation, vegetation type, tide, and specific soil types.''

The CHRT recognized that the different systems occupied by green sturgeon at specific stages of their life cycle serve distinct purposes and thus may contain different PCEs. Based on the best available scientific information, the CHRT identified PCEs for freshwater riverine systems, estuarine areas, and nearshore marine waters.

The specific PCEs essential for the conservation of the Southern DPS in freshwater riverine systems include:

(1) *Food resources.* Abundant prey items for larval, juvenile, subadult, and adult life stages. Although the CHRT lacked specific data on food resources for green sturgeon within freshwater riverine systems, juvenile green sturgeon most likely feed on fly larvae (based on nutritional studies on the closely-related white sturgeon) (J. Stuart, NMFS, 2008, pers. comm.). Food resources are important for juvenile foraging, growth, and development during their downstream migration to the Delta and bays. In addition, subadult and adult green sturgeon may forage during their downstream post-spawning migration, while holding within deep pools (Erickson *et al.*, 2002), or on non-spawning migrations within freshwater rivers. Subadult and adult green sturgeon in freshwater rivers most likely feed on benthic prey species similar to those fed on in bays and estuaries, including shrimp, clams, and benthic fishes (Moyle *et al.*, 1995; Erickson *et al.*, 2002; Moser and Lindley, 2007; Dumbauld *et al.*, 2008).

(2) *Substrate type or size (i.e., structural features of substrates).* Substrates suitable for egg deposition and development (*e.g.*, bedrock sills and shelves, cobble and gravel, or hard clean sand, with interstices or irregular surfaces to ''collect'' eggs and provide protection from predators, and free of excessive silt and debris that could smother eggs during incubation), larval development (*e.g.*, substrates with interstices or voids providing refuge from predators and from high flow conditions), and subadults and adults (*e.g.*, substrates for holding and spawning). For example, spawning is believed to occur over substrates ranging from clean sand to bedrock, with preferences for cobble (Emmett *et al.*, 1991; Moyle *et al.*, 1995). Eggs likely adhere to substrates, or settle into crevices between substrates (Deng, 2000; Van Eenennaam *et al.*, 2001; Deng *et al.*, 2002). Both embryos and larvae exhibited a strong affinity for benthic structure during laboratory studies (Van Eenennaam *et al.*, 2001; Deng *et al.*, 2002; Kynard *et al.*, 2005), and may seek refuge within crevices, but use flat-surfaced substrates for foraging (Nguyen and Crocker, 2007). For more details, see the sections on ''Spawning'' and ''Development of early life stages''.

(3) *Water flow.* A flow regime (*i.e.*, the magnitude, frequency, duration, seasonality, and rate-of-change of fresh water discharge over time) necessary for normal behavior, growth, and survival of all life stages. Such a flow regime should include stable and sufficient water flow rates in spawning and rearing reaches to maintain water temperatures within the optimal range for egg, larval, and juvenile survival and development (11–19 °C) (Cech *et al.*, 2000, cited in COSEWIC, 2004; Mayfield and Cech, 2004; Van Eenennaam *et al.*, 2005; Allen *et al.*, 2006). Sufficient flow is needed to reduce the incidence of fungal infestations of the eggs (Deng *et al.*, 2002; Parsley *et al.*, 2002). In addition, sufficient flow is needed to flush silt and debris from cobble, gravel, and other substrate surfaces to prevent crevices from being filled in (and potentially suffocating the eggs; Deng *et al.*, 2002) and to maintain surfaces for feeding (Nguyen and Crocker, 2007). Successful migration of adult green sturgeon to and from spawning grounds is also dependent on sufficient water flow. As stated in the subsection titled ''Spawning'', spawning success is most certainly associated with water flow and water temperature. Spawning in the Sacramento River is believed to be triggered by increases in water flow to about 400 m^3/s (average daily water flow during spawning months: 198–306 m^3/s) (Brown, 2007). Post-spawning downstream migrations are triggered by increased flows, ranging from 174–417 m^3/s in the late summer (Vogel, 2005) and greater than 100 m^3/s in the winter (Erickson *et al.*, 2002; Benson *et al.*, 2007; M. Thomas and R. Corwin, USBR, 2008, pers. comm.).

(4) *Water quality.* Water quality, including temperature, salinity, oxygen content, and other chemical characteristics, necessary for normal behavior, growth, and viability of all life stages (see sections on ''Development of early life stages'' and ''Adults and subadults''). Suitable water temperatures would include: Stable water temperatures within spawning reaches (wide fluctuations could increase egg mortality or deformities in developing embryos); temperatures within 11–17 °C (optimal range = 14–16 °C) in spawning reaches for egg incubation (March–August) (Van Eenennaam *et al.*, 2005); temperatures below 20 °C for larval development (Werner *et al.*, 2007); and temperatures below 24 °C for juveniles (Mayfield and Cech, 2004; Allen *et al.*, 2006a). Suitable salinity levels range from fresh water (< 3 parts per thousand (ppt)) for larvae and early juveniles (about 100 dph) to brackish water (10 ppt) for juveniles prior to their transition to salt water. Prolonged exposure to higher salinities may result in decreased growth and activity levels and even mortality (Allen and Cech, 2007). Adequate levels of dissolved oxygen are needed to support oxygen consumption by fish in their early life stages (ranging from 61.78 to 76.06 mg O_2 hr^{-1} kg^{-1} for juveniles) (Allen and Cech, 2007). Suitable water quality would also include water containing acceptably low levels of contaminants (*i.e.*, pesticides, organochlorines, elevated levels of heavy metals, etc.; acceptably low levels would be determined by NMFS on a case-by-case basis) that may disrupt normal development of embryonic, larval, and juvenile stages of green sturgeon. Water with acceptably low levels of such contaminants would protect green sturgeon from adverse impacts on growth, reproductive development, and reproductive success (*e.g.*, reduced egg size and abnormal gonadal development) likely to result

from exposure to contaminants (Fairey *et al.*, 1997; Foster *et al.*, 2001a; Foster *et al.*, 2001b; Kruse and Scarnecchia, 2002; Feist *et al.*, 2005; Greenfield *et al.*, 2005).

(5) *Migratory corridor.* A migratory pathway necessary for the safe and timely passage of Southern DPS fish within riverine habitats and between riverine and estuarine habitats (*e.g.*, an unobstructed river or dammed river that still allows for safe and timely passage). We define safe and timely passage to mean that human-induced impediments, either physical, chemical or biological, do not alter the migratory behavior of the fish such that its survival or the overall viability of the species is compromised (*e.g.*, an impediment that compromises the ability of fish to reach their spawning habitat in time to encounter con-specifics and reproduce). Unimpeded migratory corridors are necessary for adult green sturgeon to migrate to and from spawning habitats, and for larval and juvenile green sturgeon to migrate downstream from spawning/rearing habitats within freshwater rivers to rearing habitats within the estuaries.

(6) *Water depth.* Deep (≥ 5 m) holding pools for both upstream and downstream holding of adult or subadult fish, with adequate water quality and flow to maintain the physiological needs of the holding adult or subadult fish (see section titled Adults and Subadults). Deep pools of ≥ 5 m depth with high associated turbulence and upwelling are critical for adult green sturgeon spawning and for summer holding within the Sacramento River (R. Corwin, USBR, and B. Poytress, USFWS, 2008, pers. comm.). Adult green sturgeon in the Klamath and Rogue rivers also occupy deep holding pools for extended periods of time, presumably for feeding, energy conservation, and/or refuge from high water temperatures (Erickson *et al.*, 2002; Benson *et al.*, 2007).

(7) *Sediment quality.* Sediment quality (*i.e.*, chemical characteristics) necessary for normal behavior, growth, and viability of all life stages. This includes sediments free of elevated levels of contaminants (*e.g.*, selenium, polyaromatic hydrocarbons (PAHs), and organochlorine pesticides) that may adversely affect green sturgeon. Based on studies of white sturgeon, bioaccumulation of contaminants from feeding on benthic species may adversely affect the growth, reproductive development, and reproductive success of green sturgeon (see section titled Adult and Subadults).

The specific PCEs essential for the conservation of the Southern DPS in estuarine areas include:

(1) *Food resources.* Abundant prey items within estuarine habitats and substrates for juvenile, subadult, and adult life stages. As described previously (see *Green Sturgeon Natural History*), prey species for juvenile, subadult, and adult green sturgeon within bays and estuaries primarily consist of benthic invertebrates and fishes, including crangonid shrimp, burrowing thalassinidean shrimp (particularly the burrowing ghost shrimp), amphipods, isopods, clams, annelid worms, crabs, sand lances, and anchovies. These prey species are critical for the rearing, foraging, growth, and development of juvenile, subadult, and adult green sturgeon within the bays and estuaries.

(2) *Water flow.* Within bays and estuaries adjacent to the Sacramento River (*i.e.*, the Sacramento-San Joaquin Delta and the Suisun, San Pablo, and San Francisco bays), sufficient flow into the bay and estuary to allow adults to successfully orient to the incoming flow and migrate upstream to spawning grounds. Sufficient flows are needed to attract adult green sturgeon to the Sacramento River to initiate the upstream spawning migration (Kohlhorst *et al.*, 1991, cited in CDFG, 2002; J. Stuart, NMFS, 2008, pers. comm.).

(3) *Water quality.* Water quality, including temperature, salinity, oxygen content, and other chemical characteristics, necessary for normal behavior, growth, and viability of all life stages. Suitable water temperatures for juvenile green sturgeon should be below 24 °C. At temperatures above 24 °C, juvenile green sturgeon exhibit decreased swimming performance (Mayfield and Cech, 2004) and increased cellular stress (Allen *et al.*, 2006). Suitable salinities range from brackish water (10 ppt) to salt water (33 ppt). Juveniles transitioning from brackish to salt water can tolerate prolonged exposure to salt water salinities, but may exhibit decreased growth and activity levels (Allen and Cech, 2007), whereas subadults and adults tolerate a wide range of salinities (Kelly *et al.*, 2007). Subadult and adult green sturgeon occupy a wide range of dissolved oxygen levels, but may need a minimum dissolved oxygen level of at least 6.54 mg O_2/l (Kelly *et al.*, 2007; Moser and Lindley, 2007). As described above, adequate levels of dissolved oxygen are also required to support oxygen consumption by juveniles (ranging from 61.78 to 76.06 mg O_2 hr^{-1} kg^{-1}) (Allen and Cech, 2007). Suitable water quality also includes water with acceptably low levels of contaminants (*e.g.*, pesticides, organochlorines, elevated levels of heavy metals; acceptable low levels as determined by NMFS on a case-by-case basis) that may disrupt the normal development of juvenile life stages, or the growth, survival, or reproduction of subadult or adult stages.

(4) *Migratory corridor.* A migratory pathway necessary for the safe and timely passage of Southern DPS fish within estuarine habitats and between estuarine and riverine or marine habitats. We define safe and timely passage to mean that human-induced impediments, either physical, chemical or biological, do not alter the migratory behavior of the fish such that its survival or the overall viability of the species is compromised (*e.g.*, an impediment that compromises the ability of fish to reach thermal refugia by the time they enter a particular life stage). Within the bays and estuaries adjacent to the Sacramento River, unimpeded passage is needed for juvenile green sturgeon to migrate from the river to the bays and estuaries and eventually out into the ocean. Passage within the bays and the Delta is also critical for adults and subadults for feeding and summer holding, as well as to access the Sacramento River for their upstream spawning migrations and to make their outmigration back into the ocean. Within bays and estuaries outside of the Delta and the Suisun, San Pablo, and San Francisco bays, unimpeded passage is necessary for adult and subadult green sturgeon to access feeding areas, holding areas, and thermal refugia, and to ensure passage back out into the ocean.

(5) *Water depth.* A diversity of depths necessary for shelter, foraging, and migration of juvenile, subadult, and adult life stages. Subadult and adult green sturgeon occupy a diversity of depths within bays and estuaries for feeding and migration. Tagged adults and subadults within the San Francisco Bay estuary primarily occupied waters over shallow depths of less than 10 m, either swimming near the surface or foraging along the bottom (Kelly *et al.*, 2007). In a study of juvenile green sturgeon in the Delta, relatively large numbers of juveniles were captured primarily in shallow waters from 1–3 meters deep, indicating juveniles may require even shallower depths for rearing and foraging (Radtke, 1966). Thus, a diversity of depths is important to support different life stages and habitat uses for green sturgeon within estuarine areas.

(6) *Sediment quality.* Sediment quality (*i.e.*, chemical characteristics) necessary for normal behavior, growth, and viability of all life stages. This includes sediments free of elevated levels of contaminants (*e.g.*, selenium, PAHs, and organochlorine pesticides) that can cause adverse effects on all life stages of green sturgeon (see description of ''Sediment quality'' for riverine habitats above).

The specific PCEs essential for the conservation of the Southern DPS in coastal marine areas include:

(1) *Migratory corridor.* A migratory pathway necessary for the safe and timely passage of Southern DPS fish within marine and between estuarine and marine habitats. We define safe and timely passage to mean that human-induced impediments, either physical, chemical or biological, do not alter the migratory behavior of the fish such that its survival or the overall viability of the species is compromised (*e.g.*, an impediment that compromises the ability of fish to reach abundant prey resources during the summer months in Northwest Pacific estuaries). Subadult and adult green sturgeon spend the majority of their time in marine and estuarine waters outside of their natal rivers. Unimpeded passage within coastal marine waters is critical for subadult and adult green sturgeon to access oversummering habitats within coastal bays and estuaries and overwintering habitat within coastal waters between Vancouver Island, BC, and southeast Alaska. Access to and unimpeded movement within these areas is also necessary for green sturgeon to forage for prey and make lengthy migrations necessary to reach other foraging areas (Lindley *et al.*, 2008). Passage is also necessary for subadults and adults to migrate back to San Francisco Bay and to the Sacramento River for spawning.

(2) *Water quality.* Coastal marine waters with adequate dissolved oxygen levels and acceptably low levels of contaminants (*e.g.*, pesticides, organochlorines, heavy metals that may disrupt the normal behavior, growth, and viability of subadult and adult green sturgeon). Based on studies of tagged subadult and adult green sturgeon in the San Francisco Bay estuary, CA, and Willapa Bay, WA, subadults and adults may need a minimum dissolved oxygen level of at least 6.54 mg O_2/l (Kelly *et al.*, 2007; Moser and Lindley, 2007). As described above, exposure to and bioaccumulation of contaminants may adversely affect the growth, reproductive development, and reproductive success of subadult and adult green sturgeon. Thus, waters with acceptably low levels of such contaminants (as determined by NMFS on a case-by-case basis) are required for the normal development of green sturgeon for optimal survival and spawning success.

(3) *Food resources.* Abundant prey items for subadults and adults, which may include benthic invertebrates and fishes. Green sturgeon spend more than half their lives in coastal marine and estuarine waters, spending from 3–20 years at a time out at sea. Abundant food resources are important to support subadults and adults over long-distance migrations, and may be one of the factors attracting green sturgeon to habitats far to the north (off the coast of Vancouver Island and Alaska) and to the south (Monterey Bay, CA, and off the coast of southern California) of their natal habitat. Although the CHRT lacked direct evidence, prey species likely include benthic invertebrates and fishes similar to those fed upon by green sturgeon in bays and estuaries (*e.g.*, shrimp, clams, crabs, anchovies, sand lances) (see section on ''Adults and subadults'').

Geographical Area Occupied by the Species and Specific Areas Within the Geographical Area Occupied

One of the first steps in the critical habitat designation process is to define the geographical area occupied by the species at the time of listing. The CHRT relied on data from tagging and tracking studies, genetic analyses, field observations, records of fisheries take and incidental take (*e.g.*, in water diversion activities), and opportunistic sightings to provide information on the current range and distribution of green sturgeon and of the Southern DPS. The range of green sturgeon extends from the Bering Sea, Alaska, to Enseñada, Mexico. Within this range, Southern DPS fish are confirmed to occur from Graves Harbor, Alaska, to Monterey Bay, California (Lindley *et al.*, 2008; S. Lindley and M. Moser, NMFS, 2008, unpublished data), based on telemetry data and genetic analyses. Green sturgeon have been observed northwest of Graves Harbor, AK, and south of Monterey Bay, CA, but have not been identified as belonging to either the Northern or Southern DPS. The CHRT concluded that there are no barriers or habitat conditions preventing Southern DPS fish detected in Monterey Bay, CA, or off Graves Harbor, AK, from moving further south or further north, and that the green sturgeon observed in these areas could belong to either the Northern DPS or the Southern DPS. Based on this reasoning, the geographical area occupied by the Southern DPS was defined as the entire range occupied by green sturgeon (*i.e.*, from the Bering Sea, AK, to Enseñada, Mexico), encompassing all areas where the presence of Southern DPS fish has been confirmed, as well as areas where the presence of Southern DPS fish is likely (based on the presence of confirmed Northern DPS fish or green sturgeon of unknown DPS).

Areas outside of the United States cannot be designated as critical habitat (50 CFR 424.12(h)). Thus, the occupied geographical area under consideration for this designation is limited to areas from the Bering Sea, AK, to the California/Mexico border, excluding Canadian waters. For freshwater rivers, the CHRT concluded that green sturgeon of each DPS are likely to occur throughout their natal river systems, but, within non-natal river systems, are likely to be limited to the estuaries and would not occur upstream of the head of the tide. For the purposes of our evaluation of critical habitat, we defined all green sturgeon observed upstream of the head of the tide in freshwater rivers south of the Eel River (*i.e.*, the Sacramento River and its tributaries) as belonging to the Southern DPS, and all green sturgeon observed upstream of the head of the tide in freshwater rivers north of and including the Eel River as belonging to the Northern DPS. Thus, for freshwater rivers north of and including the Eel River, the areas upstream of the head of the tide were not considered part of the geographical area occupied by the Southern DPS.

The CHRT then identified ''specific areas'' within the geographical area occupied. To be eligible for designation as critical habitat under the ESA, each specific area must contain at least one PCE that may require special management considerations or protection. For each specific occupied area, the CHRT noted whether the presence of Southern DPS green sturgeon is confirmed or likely (based on the presence of Northern DPS fish or green sturgeon of unknown DPS) and verified that each area contained one or more PCE(s) that may require special management considerations or protection. The following paragraphs provide a brief description of the presence and distribution of Southern DPS green sturgeon within each area and summarize the CHRT's methods for delineating the specific areas.

Freshwater Rivers, Bypasses, and the Delta

Green sturgeon occupy several freshwater river systems from the Sacramento River, CA, north to British Columbia, Canada (Moyle, 2002). As

described in the previous section, Southern DPS green sturgeon occur throughout their natal river systems (*i.e.*, the Sacramento River, lower Feather River, and lower Yuba River), but are believed to be restricted to the estuaries in non-natal river systems (*i.e.*, north of and including the Eel River). The CHRT defined the specific areas in the Sacramento, Feather, and Yuba rivers in California to include riverine habitat from the river mouth upstream to and including the furthest known site of historic and/or current sighting or capture of green sturgeon, as long as the site is still accessible. The specific areas were extended upstream to a geographically identifiable point. The riverine specific areas include areas that offer at least periodic passage of Southern DPS fish to upstream sites and include sufficient habitat necessary for each riverine life stage (*e.g.*, spawning, egg incubation, larval rearing, juvenile feeding, passage throughout the river, and/or passage into and out of estuarine or marine habitat).

The CHRT delineated specific areas where Southern DPS green sturgeon occur, including: the Sacramento River, the Yolo and Sutter bypasses, the lower Feather River, and the lower Yuba River. The CHRT also delineated a specific area in the Sacramento-San Joaquin Delta. The mainstem Sacramento River is the only area where spawning by Southern DPS green sturgeon has been confirmed and where all life stages of the Southern DPS are supported. Beginning in March and through early summer, adult green sturgeon migrate as far upstream as the Keswick Dam (rkm 486) to spawn (Brown, 2007). Spawning has been confirmed by the collection of larvae and juveniles at the RBDD and the Glenn-Colusa Irrigation District (GCID) (CDFG, 2002; Brown, 2007) and by the collection of green sturgeon eggs downstream of the RBDD (Brown, 2007; B. Poytress, USFWS, 2008, pers. comm.). The Sacramento River provides important spawning, holding, and migratory habitat for adults and important rearing, feeding, and migratory habitat for larvae and juveniles. The Yolo and Sutter bypasses adjacent to the lower Sacramento River also serve as important migratory corridors for Southern DPS adults, subadults, and juveniles on their upstream or downstream migration and provide a high macroinvertebrate forage base that may support green sturgeon feeding. Southern DPS adults occupy the lower Feather River up to Oroville Dam (rkm 116) and the lower Yuba River up to Daguerre Dam (rkm 19). Based on observations of Southern DPS adults occurring right up to the dams and of spawning behavior by adults on the Feather River, spawning may have occurred historically in the lower Feather River and, to a lesser extent, in the lower Yuba River. However, no green sturgeon eggs, larvae, or juveniles have ever been collected within these rivers. Further downstream, the Sacramento-San Joaquin Delta provides important rearing, feeding, and migratory habitat for juveniles, which occur throughout the Delta in all months of the year. Subadults and adults also occur throughout the Delta to feed, grow, and prepare for their outmigration to the ocean. The draft biological report provides more detailed information on each specific area, including a description of the PCEs present, special management considerations or protection that may be needed, and the presence and distribution of Southern DPS green sturgeon. The draft biological report is available upon request (see **ADDRESSES**), via our Web site at *http://swr.nmfs.noaa.gov*, or via the Federal eRulemaking Web site at *http://www.regulations.gov*. For additional discussion of the special management considerations or protection that may be needed for the PCEs, please see also the description of ''Special management considerations or protection'' below.

Bays and Estuaries

Southern DPS green sturgeon occupy coastal bays and estuaries from Monterey Bay, CA, to Puget Sound, WA. In the Central Valley, CA, juvenile, subadult, and adult life stages occur throughout the Suisun, San Pablo, and San Francisco bays. These bays support the rearing, feeding, and growth of juveniles prior to their first entry into marine waters. The bays also serve as important feeding, rearing, and migratory habitat for subadult and adult Southern DPS green sturgeon.

Outside of their natal system, subadult and adult Southern DPS fish occupy coastal bays and estuaries in California, Oregon, and Washington, including estuarine waters at the mouths of non- natal rivers. Subadult and adult Southern DPS green sturgeon have been confirmed to occupy the following coastal bays and estuaries: Monterey Bay, CA; Humboldt Bay, CA; Coos Bay, OR; Winchester Bay, OR; the lower Columbia River estuary; Willapa Bay, WA; Grays Harbor, WA; and Puget Sound, WA (Chadwick, 1959; Miller, 1972; Lindley *et al.*, 2008; Pinnix, 2008; S. Lindley and M. Moser, NMFS, 2008, unpublished data). The presence of Southern DPS green sturgeon is likely (based on limited records of confirmed Northern DPS fish or green sturgeon of unknown DPS), but not confirmed within the following coastal bays and estuaries: Elkhorn Slough, CA; Tomales Bay, CA; Noyo Harbor, CA; Eel River estuary, CA; Klamath/Trinity River estuary, CA; Rogue River estuary, OR; Siuslaw River estuary, OR; Alsea River estuary, OR; Yaquina Bay, OR; and Tillamook Bay, OR (Emmett *et al.*, 1991; Moyle *et al.*, 1992; Adams *et al.*, 2002; Erickson *et al.*, 2002; Yoklavich *et al.*, 2002; Farr and Kern, 2005).

Subadult and adult green sturgeon are believed to occupy coastal bays and estuaries outside of their natal waters for feeding, optimization of growth, and thermal refugia (Moser and Lindley, 2007; Lindley *et al.*, 2008). Occupied coastal bays and estuaries north of San Francisco Bay, CA, contain oversummering habitats for subadults and adults, whereas coastal bays and estuaries south of San Francisco Bay, CA, are believed to contain overwintering habitats (Lindley *et al.*, 2008). The largest concentrations of green sturgeon, including Southern DPS fish, occur within the lower Columbia River estuary, Willapa Bay, and Grays Harbor (Emmett *et al.*, 1991; Adams *et al.*, 2002; WDFW and ODFW, 2002; Israel and May, 2006; Moser and Lindley, 2007; Lindley *et al.*, 2008). Large numbers of green sturgeon also occur within Winchester Bay, Coos Bay, and Humboldt Bay (Moyle *et al.*, 1992; Rien *et al.*, 2000; Farr *et al.*, 2001; Adams *et al.*, 2002; Farr and Rien, 2002, 2003; Farr and Kern, 2004, 2005; Israel and May, 2006; Lindley *et al.*, 2008; Pinnix, 2008). Smaller numbers of green sturgeon occur in Tomales Bay, CA (Moyle *et al.*, 1992), Yaquina Bay (Emmett *et al.*, 1991; Rien *et al.*, 2000; Farr *et al.*, 2001; Farr and Rien, 2002, 2003; Farr and Kern, 2004, 2005), and Puget Sound, WA (S. Lindley and M. Moser, NMFS, 2008, unpublished data). Based on limited available data, green sturgeon presence is believed to be rare in the following bays and estuaries: Elkhorn Slough, CA; Noyo Harbor, CA; Siuslaw River estuary, OR; Alsea River estuary, OR; and Tillamook Bay, OR (Emmett *et al.*, 1991; Moyle *et al.*, 1992; Rien *et al.*, 2000; Farr *et al.*, 2001; Farr and Rien, 2002; Yoklavich *et al.*, 2002; Farr and Rien, 2003; Farr and Kern, 2004, 2005). Green sturgeon are present in the estuaries of the Eel River, Klamath/Trinity rivers, and Rogue River, but are believed to most likely belong to the Northern DPS. This is based on the fact that the Eel, Klamath/Trinity, and Rogue rivers are spawning rivers for the Northern DPS and that, to

date, no tagged Southern DPS subadults or adults have been detected in the estuaries of the three rivers, although Southern DPS fish have been observed in coastal marine waters just outside the mouth of the Klamath River (S. Lindley, NMFS, 2008, pers. comm.).

The CHRT included all coastal bays and estuaries for which there was evidence to confirm the presence of green sturgeon, noting where there were confirmed Southern DPS fish, confirmed Northern DPS fish, or confirmed green sturgeon of unknown DPS. As stated in the previous section, based on our definitions for the Northern DPS and Southern DPS, any green sturgeon observed upstream of the head of the tide in freshwater rivers north of and including the Eel River were assigned to the Northern DPS. Thus, areas upstream of the head of the tide on these rivers were not included as part of the occupied specific areas for the Southern DPS. Each specific area was defined to extend from the mouth of the bay or estuary upstream to the head of the tide. The boundary at the mouth of each bay or estuary was defined by the COLREGS demarcation line. COLREGS demarcation lines delineate ''those waters upon which mariners shall comply with the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) and those waters upon which mariners shall comply with the Inland Navigation Rules'' (33 CFR 80.01). Waters inside of the 72 COLREGS lines are Inland Rules waters and waters outside of the 72 COLREGS lines are COLREGS waters. The draft biological report provides additional information for each specific area. For a copy of the report, see **ADDRESSES**, our Web site at *http://swr.nmfs.noaa.gov*, or the Federal eRulemaking Web site at *http://www.regulations.gov*. For additional discussion of the special management considerations or protection that may be needed for the PCEs, please see also the description of ''Special management considerations or protection'' below.

Coastal Marine Waters

Subadult and adult green sturgeon spend most of their time in coastal marine and estuarine waters. The best available data indicate coastal marine waters are important for seasonal migrations from southern California to Alaska to reach distant foraging and aggregation areas. Green sturgeon occur primarily within the 110 m depth bathymetry (Erickson and Hightower, 2007). Green sturgeon tagged in the Rogue River and tracked in marine waters typically occupied the water column at 40–70 m depth, but made rapid vertical ascents to or near the surface, for reasons yet unknown (Erickson and Hightower, 2007). Green sturgeon use of waters < 110 m depth was confirmed by coastal Oregon and Washington bottom-trawl fisheries records indicating that most reported locations of green sturgeon occurred inside of the 110-m depth contour from 1993–2000, despite the fact that most of the fishing effort occurred in water deeper than 110 m (Erickson and Hightower, 2007).

Based on tagging studies of both Southern and Northern DPS fish, green sturgeon spend a large part of their time in coastal marine waters migrating between coastal bays and estuaries, including sustained long-distance migrations of up to 100 km per day (S. Lindley and M. Moser, NMFS, pers. comm. cited in BRT, 2005). These seasonal long-distance migrations are most likely driven by food resources. Some tagged individuals were observed swimming at slower speeds and spending several days within certain areas, suggesting that the individuals were feeding (S. Lindley and M. Moser, NMFS, 2008, pers. comm.).

Within the geographical area occupied (from the California/Mexico border to the Bering Sea, Alaska), the CHRT divided the coastal marine waters into 12 specific areas between estuaries or bays confirmed to be occupied by the Southern DPS. The presence of green sturgeon and Southern DPS fish within each area was based on data from tagging and tracking studies, records of fisheries captures, and NOAA Observer Program records. Tagged Southern DPS subadults and adults have been detected in coastal marine waters from Monterey Bay, CA, to Graves Harbor, AK, including the Strait of Juan de Fuca (Lindley *et al.*, 2008). Green sturgeon bycatch data from NOAA's West Coast Groundfish Observer Program (WCGOP) support the telemetry results, showing green sturgeon occur from Monterey Bay, CA, to Cape Flattery, WA, with the greatest catch per unit effort in coastal waters from Monterey Bay to Humboldt Bay, CA (WCGOP, 2008, unpublished data). Because green sturgeon were only observed in the bottom trawl fishery, there was no data on green sturgeon bycatch off southeast Alaska, where bottom trawl fishing is prohibited. Green sturgeon have, however, been captured in bottom trawl fisheries along the coast off British Columbia. Although critical habitat cannot be designated within Canadian waters, it is important to note that several tagged Southern DPS green sturgeon have been detected off Brooks Peninsula on the northern tip of Vancouver Island, BC (Lindley *et al.*, 2008.). Patterns of telemetry data suggest that Southern DPS fish use oversummering grounds in coastal bays and estuaries along northern California, Oregon, and Washington and overwintering grounds between Vancouver Island, BC, and southeast Alaska (Lindley *et al.*, 2008).

Based on the tagging data and the information described above regarding green sturgeon use of coastal bays and estuaries in California, Oregon, and Washington, the CHRT identified the coastal marine waters from Monterey Bay, CA, to Vancouver Island, BC, as the primary migratory/connectivity corridor for subadult and adult Southern DPS green sturgeon to migrate to and from oversummering habitats and overwintering habitats. Coastal marine waters off southeast Alaska were not considered part of the primary migratory/connectivity corridor for green sturgeon, but were recognized as an important area at the northern extent of the overwintering range, based on the detection of two tagged Southern DPS fish off Graves Harbor, AK, (S. Lindley, NMFS, and J. Israel, UC Davis, 2007, pers. comm.) and green sturgeon bycatch data along the northern coast of British Columbia (Lindley *et al.*, 2008). For areas northwest of southeast Alaska and south of Monterey Bay, CA, data on green sturgeon occurrence include the 2006 capture of two green sturgeon of unknown DPS in bottom trawl groundfish fisheries off Kodiak Island, AK, and in the Bering Sea off Unimak Island, AK (J. Ferdinand and D. Stevenson, NMFS, 2006, pers. comm.). In coastal marine waters south of Monterey Bay, a few green sturgeon of unknown DPS have been captured off Huntington Beach and Newport (Roedel, 1941), Point Vicente (Norris, 1957), Santa Barbara, and San Pedro (R. Rasmussen, NMFS, 2006, pers. comm.). More detailed information on the specific areas within coastal marine waters can be found in the draft biological report, available at our Web site at *http://swr.nmfs.noaa.gov*, at the Federal eRulemaking Web site at *http://www.regulations.gov*, or upon request (see **ADDRESSES**). For additional discussion of the special management considerations or protection that may be needed for the PCEs, please see also the description of ''Special management considerations or protection'' below.

Special Management Considerations or Protection

Joint NMFS and USFWS regulations at 50 CFR 424.02(j) define ''special management considerations or protection'' to mean ''any methods or

procedures useful in protecting physical and biological features of the environment for the conservation of listed species.'' Based on discussions with the CHRT and consideration of the draft economic report, a number of activities were identified that may threaten the PCEs such that special management considerations or protection may be required. Major categories of habitat-related activities include: (1) Dams; (2) water diversions; (3) dredging and disposal of dredged material; (4) in-water construction or alterations, including channel modifications/diking, sand and gravel mining, gravel augmentation, road building and maintenance, forestry, grazing, agriculture, urbanization, and other activities; (5) National Pollutant Discharge Elimination System (NPDES) permit activities and activities generating non-point source pollution; (6) power plants; (7) commercial shipping; (8) aquaculture; (9) desalination plants; (10) proposed alternative energy projects; (11) liquefied natural gas (LNG) projects; (12) bottom trawling; and (13) habitat restoration. These activities may have an effect on one or more PCE(s) via their alteration of one or more of the following: Stream hydrology, water level and flow, water temperature, dissolved oxygen, erosion and sediment input/transport, physical habitat structure, vegetation, soils, nutrients and chemicals, fish passage, and stream/estuarine/marine benthic biota and prey resources. The CHRT identified the activities occurring within each specific area that may necessitate special management considerations or protection for the PCEs and these are described briefly in the following paragraphs. These activities are documented more fully in the draft biological report.

Table 1 lists the specific areas and the river miles or area (square miles) covered, the PCEs present, and the activities that may affect the PCEs for each specific area and necessitate the need for special management considerations or protection. Several activities may affect the PCEs within the freshwater rivers, bypasses, and the Delta. Within the rivers, dams and diversions pose threats to habitat features essential for the Southern DPS by obstructing migration, alterating water flows and temperature, and modifying substrate composition within the rivers. Pollution from agricultural runoff and water returns, as well as from other point and non-point sources, adversely affects water quality within the rivers, bypasses and the Delta. Water management practices in the bypasses may pose a threat to Southern DPS fish residing within or migrating through the bypasses. For example, low water levels may obstruct passage through the bypasses, resulting in stranded fish. Within the Delta, activities such as dredging, pile driving, water diversion, and the discharge of pollutants from point and non-point sources can adversely affect water quality as well as alter the composition and distribution of bottom substrates within the Delta.

Activities were also identified that may threaten the PCEs in coastal bays and estuaries and may necessitate the need for special management considerations or protection (Table 1). The application of pesticides may adversely affect prey resources and water quality within the bays and estuaries. In Willapa Bay and Grays Harbor, WA, the use of carbaryl in association with aquaculture operations reduces the abundance and availability of burrowing ghost shrimp, an important prey species for green sturgeon (Moser and Lindley, 2007; Dumbauld *et al.*, 2008). In the San Francisco, San Pablo, and Suisun bays, several pesticides have been detected at levels exceeding national benchmarks for the protection of aquatic life (Domagalski *et al.*, 2000). These pesticides pose a water quality issue and may affect the abundance and health of prey items as well as the growth and reproductive health of Southern DPS green sturgeon through bioaccumulation. Other activities of concern include those that may disturb bottom substrates, adversely affect prey resources, or degrade water quality through resuspension of contaminated sediments (*e.g.*, dredging operations, in-water construction).

In addition, several activities were identified that may affect the PCEs within coastal marine areas such that the PCEs would require special management consideration or protection (Table 1). The fact that green sturgeon were only captured in the bottom trawl fishery (based on the WCGOP bycatch data) provides evidence that green sturgeon are associated with the benthos and thus exposed to activities that disturb the bottom. Of particular concern are activities that affect prey resources. Prey resources likely include species similar to those fed on by green sturgeon in bays and estuaries (*e.g.*, burrowing ghost shrimp, mud shrimp, crangonid shrimp, amphipods, isopods, Dungeness crab), and these prey resources are known to occur within the marine specific areas. Activities that can affect these prey resources include: Commercial shipping and activities generating point source pollution (subject to National Pollutant Discharge Elimination System requirements) and non-point source pollution that can discharge contaminants and result in bioaccumulation of contaminants in green sturgeon; disposal of dredged materials that can bury prey resources; and bottom trawl fisheries that can disturb the bottom (but may result in beneficial or adverse effects on prey resources for green sturgeon). In addition, petroleum spills from commercial shipping activities and proposed tidal and wave energy projects may affect water quality or hinder the migration of green sturgeon along the coast and may necessitate special management of the PCEs.

Table 1. Summary of occupied specific areas within freshwater rivers, the bypasses, the Sacramento-San Joaquin Delta, coastal bays and estuaries, and coastal marine areas (within 110 m depth). The river miles or surface area covered, the PCEs present, and activities that may affect the PCEs and necessitate the need for special management considerations or protection within each area are listed. PCEs: Wd = depth, Fd = food, Fl = water flow, P = passage, S = substrates, Sq = sediment quality, Wq = water quality. Activities: AG = agriculture, AQ = aquaculture, BOT = bottom trawl fishing, CON = in-water construction or alterations, DAM = dams, DESAL = desalination plants, DIV = water diversions, DR = dredging and deposition of dredged material, EP = tidal/wave energy projects, LNG = LNG projects, POLL = point and non-point source pollution, PP = power plants, REST = restoration, SHIP = commercial shipping.

Specific area	River miles	PCEs present	Activities
Freshwater rivers			
Upper Sacramento River, CA	58.9	Wd, Fd, Fl, P, S, Sq, Wq	CON, DAM, DIV, POLL.
Lower Sacramento River, CA	182.4	Wd, Fd, Fl, P, S, Sq, Wq	AG, CON, DAM, DIV, DR, POLL.
Lower Feather River, CA	72.7	Wd, Fl, P, Wq	AG, CON, DAM, DIV, POLL.

Specific area	River miles	PCEs present	Activities
Lower Yuba River, CA	11.5	Wd, Fl, P, Wq	AG, DAM, DIV, POLL.

Specific area	Area (sq miles)	PCEs present	Activities
Bypasses and the Delta			
Yolo Bypass, CA	112.3	Fd, P, Sq, Wq	AG.
Sutter Bypass, CA	23.5	Fd, P, Sq, Wq	AG.
Sacramento-San Joaquin Delta, CA	438.9	Wd, Fd, Fl, P, S, Sq, Wq	CON, DIV, DR, POLL, PP, REST.
Coastal Bays and Estuaries			
Elkhorn Slough, CA	1.0	Fd, Sq, P, Wq	DR, PP.
Suisun Bay, CA	50.8	Wd, Fd, Fl, P, Sq, Wq	CON, DR, REST.
San Pablo Bay, CA	127.7	Wd, Fd, P, Sq, Wq	CON, DR, POLL, PP, REST.
San Francisco Bay, CA	269.9	Wd, Fd, P, Sq, Wq	CON, DR, EP, POLL, PP, REST.
Tomales Bay, CA	11.5	Fd, P, Sq, Wq	DIV, POLL, REST.
Noyo Harbor, CA	<0.1	Fd, P, Sq, Wq	DR, POLL.
Eel R. Estuary, CA	8.5	Fd, P, Sq, Wq	CON, POLL.
Humboldt Bay, CA	26.6	Fd, P, Sq, Wq	AQ, POLL.
Klamath/Trinity R. Estuary, CA	2.5	Fd, P, Sq, Wq	CON.
Rogue R. Estuary, OR	0.6	Fd, P, Sq, Wq	CON, POLL.
Coos Bay, OR	17.7	Fd, P, Sq, Wq	CON, LNG, POLL.
Winchester Bay, OR	10.8	Fd, P, Sq, Wq	CON, POLL.
Siuslaw R. Estuary, OR	0.4	Fd, P, Sq, Wq	CON, POLL.
Alsea R. Estuary, OR	0.8	Fd, P, Sq, Wq	CON, DIV, POLL.
Yaquina Bay, OR	6.3	Fd, P, Sq, Wq	POLL.
Tillamook Bay, OR	14.2	Fd, P, Sq, Wq	CON, POLL.
Columbia R. Estuary, OR and WA	236.9	Fd, P, Sq, Wq	CON, DAM, DR, LNG, POLL.
Willapa Bay, WA	134.3	Fd, P, Sq, Wq	AQ, CON, EP, POLL.
Grays Harbor, WA	91.8	Fd, P, Sq, Wq	AQ, POLL, SHIP.
Puget Sound, WA	1,017.8	Fd, P, Sq, Wq	CON, DR, EP, POLL, SHIP.
Coastal Marine Waters within 110 meters depth			
CA/Mexico Border to Monterey Bay, CA	2,522.8	Fd, P, Wq	BOT, CON, DESAL, DR, EP, LNG, POLL, PP.
Monterey Bay, CA, to San Francisco Bay, CA.	1,495.9	Fd, P, Wq	BOT, DESAL, POLL, PP.
San Francisco Bay, CA, to Humboldt Bay, CA.	2,066.7	Fd, P, Wq	BOT, EP, POLL.
Humboldt Bay, CA, to Coos Bay, OR	1,911.6	Fd, P, Wq	BOT, DR, EP, POLL.
Coos Bay, OR, to Winchester Bay, OR	186.5	Fd, P, Wq	BOT, EP.
Winchester Bay, OR, to Columbia R. Estuary.	2,686.3	Fd, P, Wq	BOT, EP, POLL.
Columbia R. Estuary to Willapa Bay, WA	477.1	Fd, P, Wq	BOT.
Willapa Bay, WA, to Grays Harbor, WA	403.0	Fd, P, Wq	BOT.
Grays Harbor, WA, to WA/Canada Border.	1,900.9	Fd, P, Wq	BOT, EP, POLL.
Strait of Juan De Fuca, WA	798.8	Fd, P, Wq	BOT, DR, POLL.
Canada/AK Border to Yakutat Bay, AK	19,567.9	Fd, P, Wq	EP, POLL, SHIP.
Coastal Alaskan Waters Northwest of Yakutat Bay, AK, including the Bering Sea to the Bering Strait.	374,826.4	Fd, P, Wq	BOT, EP, LNG, SHIP.

Unoccupied Areas

Section 3(5)(A)(ii) of the ESA authorizes the designation of ''specific areas outside the geographical area occupied at the time [the species] is listed'' if these areas are essential for the conservation of the species. Regulations at 50 CFR 424.12(e) emphasize that the agency ''shall designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species.'' The CHRT considered that a critical habitat designation limited to presently occupied areas may not be sufficient for conservation, because such a designation would not address one of the major threats to the population identified by the Status Review Team—the concentration of spawning into one spawning river (*i.e.*, the Sacramento River), and, as a consequence, the risk of extirpation due to a catastrophic event.

The CHRT identified seven unoccupied areas in the Central Valley, California that may provide additional spawning habitat for the Southern DPS of green sturgeon and considered whether these areas are essential for the conservation of the Southern DPS. These seven areas include areas behind dams that are currently inaccessible to green sturgeon and areas below dams that are not currently occupied by green sturgeon. The areas include: (1) Reaches upstream of Oroville Dam on the Feather River; (2) reaches upstream of Daguerre Dam on the Yuba River; (3) areas on the Pit River upstream of Keswick and Shasta dams; (4) areas on the McCloud River upstream of Keswick

and Shasta dams; (5) areas on the upper Sacramento River upstream of Keswick and Shasta dams; (6) reaches on the American River; and (7) reaches on the San Joaquin River. Of these seven areas, the CHRT identified reaches upstream of Daguerre Dam on the Yuba River as the most important for conserving the species because: (1) The current habitat conditions are likely to support spawning; (2) adult Southern DPS fish currently occupy habitat just below the Daguerre Dam; (3) although the Yuba River is part of the Sacramento River drainage basin, it is separated spatially from the current, single spawning population on the upper Sacramento River such that if a catastrophic mortality event were to occur in the upper Sacramento River, a Yuba River population could help safeguard the species from a mortality event that would likely have significant adverse species-level effects; and (4) there is a greater potential for removal of the Daguerre Dam, or restoration of fish passage at the dam, in the near future than for any of the other dams located within the unoccupied areas identified by the CHRT. The CHRT also considered reaches on the San Joaquin River, from the South Delta to the Goodwin Dam on the Stanislaus River, as important for conserving the Southern DPS for some of the same reasons mentioned above, especially because the San Joaquin and Stanislaus rivers are part of an entirely different drainage basin than the current single spawning area in the upper Sacramento River. However, the CHRT was less certain regarding the prospects for reestablishing a spawning population in this area, because current conditions on the mainstem San Joaquin River are poor and it is uncertain whether conditions favorable for green sturgeon presence and spawning could be restored in this area in the near future.

The CHRT was unable to determine that these seven unoccupied areas which may be essential, actually are essential to the conservation of the Southern DPS at this time. Thus, these seven unoccupied areas are not proposed for designation as critical habitat. The CHRT believed it likely that at least one additional spawning area is needed to support the conservation of the Southern DPS, but because of insufficient information regarding: (1) The historical use of the currently unoccupied areas by green sturgeon; and (2) the likelihood that the habitats within these unoccupied areas will be restored to conditions that would support green sturgeon presence and spawning (*e.g.,* restoring fish passage and sufficient water flows and water temperatures) they were unable to determine which of these unoccupied areas would be essential for conserving the species. The development of a recovery plan could help address the latter question by establishing recovery actions (*e.g.,* removal of barriers on the Yuba River) and recovery criteria (*e.g.,* establishing at least two additional spawning populations for the Southern DPS in rivers south of the Eel River) in order to achieve downlisting and eventual delisting of the Southern DPS. NMFS encourages actions that would protect, conserve, and/or enhance habitat conditions for the Southern DPS (*e.g.,* habitat restoration, removal of dams, and establishment of fish passage) within these areas. We request additional information from the public regarding these presently unoccupied areas and their historical, current, and potential use by green sturgeon. Additional information would inform our consideration of these areas for the final designation as well as future recovery planning for the Southern DPS.

Military Lands

Under the Sikes Act of 1997 (Sikes Act) (16 U.S.C. 670a), ''each military installation that includes land and water suitable for the conservation and management of natural resources'' is required to develop and implement an integrated natural resources management plan (INRMP). An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found there. Each INRMP includes: an assessment of the ecological needs on the military installation, including the need to provide for the conservation of listed species; a statement of goals and priorities; a detailed description of management actions to be implemented to provide for these ecological needs; and a monitoring and adaptive management plan. Each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management, fish and wildlife habitat enhancement or modification, wetland protection, enhancement, and restoration where necessary to support fish and wildlife and enforcement of applicable natural resource laws.

The ESA was amended by the National Defense Authorization Act for Fiscal Year 2004 (Pub. L.108–136) to address the designation of military lands as critical habitat. ESA section 4(a)(3)(B)(i) states: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

We contacted the Department of Defense (DOD) and requested information on all INRMPs for DOD facilities that overlap with the specific areas considered for designation as critical habitat and that might provide benefits to green sturgeon. The INRMPs for one facility in California (Camp San Luis Obispo) and for nine facilities in Puget Sound, WA, were provided to us. Of these, the following six facilities with INRMPs were determined to overlap with the specific areas under consideration for critical habitat designation (all located in Puget Sound, WA): (1) Bremerton Naval Hospital; (2) Naval Air Station, Everett; (3) Naval Magazine Indian Island; (4) Naval Fuel Depot, Manchester; (5) Naval Undersea Warfare Center, Keyport; and (6) Naval Air Station, Whidbey Island. We reviewed the INRMPs for measures that would benefit green sturgeon. The INRMPs for four of the facilities (Bremerton Naval Hospital, NAS Everett, Naval Fuel Depot (Manchester), and Naval Magazine (Indian Island)) contain measures for listed salmon and bull trout that provide benefits for green sturgeon. The INRMPs for the two remaining facilities (NAS Whidbey Island and NUWC Keyport) do not contain specific requirements for listed salmon or bull trout, but also include measures that benefit fish species, including green sturgeon. Examples of the types of benefits include measures to control erosion, protect riparian zones and wetlands, minimize stormwater and construction impacts, and reduce contaminants. Based on these benefits provided for green sturgeon under the INRMPs, we determined that the areas within these six DOD facilities in Puget Sound, WA, were not eligible for designation as critical habitat.

Application of ESA Section 4(b)(2)

Section 4(b)(2) of the ESA requires the Secretary to consider the economic, national security, and any other relevant impacts of designating any particular area as critical habitat. Any particular area may be excluded from critical habitat if the Secretary determines that the benefits of excluding the area outweigh the benefits of designating the area. The Secretary may not exclude a particular area from designation if exclusion will result in the extinction of the species. Because the authority to

exclude is discretionary, exclusion is not required for any areas. In this proposed designation, the Secretary has applied his statutory discretion to exclude 13 occupied areas from critical habitat where the benefits of exclusion outweigh the benefits of designation.

The first step in conducting the ESA section 4(b)(2) analysis is to identify the ''particular areas'' to be analyzed. Where we considered economic impacts and weighed the economic benefits of exclusion against the conservation benefits of designation, we used the same biologically-based ''specific areas'' we identified in the previous sections pursuant to section 3(5)(A) of the ESA (*e.g.,* the upper Sacramento River, the lower Sacramento River, the Delta, etc.). Delineating the ''particular areas'' as the same units as the ''specific areas'' allowed us to most effectively consider the conservation value of the different areas when balancing conservation benefits of designation against economic benefits of exclusion. At this time, we have not identified any national security or other relevant impacts of designation; therefore, we did not delineate any particular areas on the basis of these impacts.

The next step in the ESA section 4(b)(2) analysis involves identification of the impacts of designation: the benefits of designation and the benefits of exclusion, and then a more in-depth discussion of each. We then weigh the benefits of designation against the benefits of exclusion, identify areas eligible for exclusion where the benefits of exclusion outweigh the benefits of designation, and determine which areas are appropriate to propose for exclusion. These steps and the resulting list of areas excluded from designation are described in detail in the sections below.

Impacts of Designation

The primary impact of a critical habitat designation stems from the requirement under section 7(a)(2) of the ESA that Federal agencies insure their actions are not likely to result in the destruction or adverse modification of critical habitat. Determining this impact is complicated by the fact that section 7(a)(2) contains the overlapping requirement that Federal agencies must also ensure their actions are not likely to jeopardize the species' continued existence. One incremental impact of designation is the extent to which Federal agencies modify their actions to insure their actions are not likely to adversely modify the critical habitat of the species, beyond any modifications they would make because of the listing and the jeopardy requirement. When a modification would be required due to impacts to both the species and critical habitat, the impact of the designation may be co-extensive with the ESA listing of the species. Additional impacts of designation include state and local protections that may be triggered as a result of the designation and the benefits from educating the public about the importance of each area for species conservation. The benefits of designation were evaluated by considering the conservation value of each occupied specific area to the Southern DPS. In the ''Benefits of Designation'' section below, we discuss how the conservation values of the specific areas were assessed.

In determining the impacts of designation, we predicted the incremental change in Federal agency actions as a result of the critical habitat designation and the adverse modification prohibition, beyond the changes predicted to occur as a result of listing and the jeopardy provision. In recent critical habitat designations for salmon and steelhead and for Southern Resident killer whales, the ''co-extensive'' impact of designation was considered in accordance with a Tenth Circuit Court decision (*New Mexico Cattle Growers Association* v. *U.S. Fish and Wildlife Service,* 248 F.3d 1277 (10th Cir. 2001)) (*NMCA*). The ''co-extensive'' impact of designation considers the predicted change in the Federal agency action resulting from the critical habitat designation and the adverse modification prohibition (whereby the action's effect on the PCEs and the value of the habitat is analyzed), even if the same change would result from application of the listing and the jeopardy provision (whereby the action's effect on the species itself and individual members of the species is analyzed). Shortly after the *NMCA* decision, however, the Court of Appeals for the Fifth Circuit (*Sierra Club* v. *U.S. Fish and Wildlife Service,* 243 F.3d 434 (5th Cir. 2001) (*Sierra Club*)) and the Court of Appeals for the Ninth Circuit (*Gifford Pinchot Task Force* v. *FWS,* 378 F.3d 1059 (9th Cir. 2004)) (*Gifford Pinchot*) invalidated our regulatory definition of ''adverse modification'' of critical habitat. Following that decision, a District Court in Washington, D.C. issued a decision involving the USFWS's critical habitat designation for the piping plover (*Cape Hatteras Access Preservation Alliance* v. *Norton,* 344 F. Supp. 2d 1080 (D.D.C. 2004)) (*Cape Hatteras*). In that decision, the Court reasoned that the impact of a regulation should be based on a comparison of the world with and without the action, and that the effects of listing and the jeopardy provision should not be considered as part of the impacts of a designation in the ESA 4(b)(2) analysis for a critical habitat designation.

Consistent with the *Cape Hatteras* decision, we estimated and analyzed the incremental impacts of designation, beyond the impacts that would result from the listing and jeopardy provision. Our methods for estimating the impacts of designation for economic impacts are summarized in the section below titled ''Determining the Benefits of Excluding Particular Areas.'' Because section 4(b)(2) requires a balancing of competing considerations, we have concluded that we must uniformly consider impacts and benefits. Though we do not propose exclusions based on national security impacts or other relevant impacts, we would also focus on incremental impacts in such an analysis. We recognize that excluding an area from designation will not likely avoid all of the impacts because the jeopardy provision under section 7 still applies. Similarly, much of the section 7 benefit would still apply because the jeopardy provision still applies.

A draft economic report describes in more detail the types of activities that may be affected by the designation, the potential range of changes we might seek in those actions, and the estimated economic impacts that might result from such changes. A draft biological report describes in detail the CHRT's evaluation of the conservation value of each specific area and reports the final conservation value ratings. The draft ESA 4(b)(2) report describes the weighing of the benefits of designation against the benefits of exclusion for each area. We solicit comments on all of these reports, available on the NMFS Southwest Region Web site at *http://swr.nmfs.noaa.gov/,* on the Federal E-Rulemaking Web site at *http://www.regulations.gov,* or upon request (see **ADDRESSES**).

Benefits of Designation

The primary benefit of designation is the protection afforded under section 7 of the ESA, requiring all Federal agencies to insure their actions are not likely to destroy or adversely modify designated critical habitat. This is in addition to the requirement that all Federal agencies ensure their actions are not likely to jeopardize the continued existence of the species. In addition, the designation may provide education and outreach benefits by informing the public about areas and features important to species conservation. By delineating areas of high conservation value, the designation may help focus

and contribute to conservation efforts for green sturgeon and their habitats.

These benefits are not directly comparable to the costs of designation for purposes of conducting the section 4(b)(2) analysis described below. Ideally, the benefits should be monetized. With sufficient information, it may be possible to monetize the benefits of a critical habitat designation by first quantifying the benefits expected from an ESA section 7 consultation and translating that into dollars. We are not aware, however, of any available data that would support such an analysis for green sturgeon (*e.g.,* estimates of the monetary value associated with conserving the PCEs within areas designated as critical habitat, or with education and outreach benefits). As an alternative approach, we used the CHRT's conservation value ratings to represent the qualitative conservation benefits of designation for each of the particular areas identified as critical habitat for the Southern DPS (see the section titled Methods for Assessment of Specific Areas). These conservation value ratings represent the estimated incremental benefit of designating critical habitat for the species. In evaluating the conservation value of each specific area, the CHRT focused on the habitat features present in, habitat functions provided by each area, and the importance of protecting the habitat for the overall conservation of the species. The draft biological report sets forth detailed information on the qualitative conservation benefits of the specific areas proposed for designation, which is summarized briefly in the following paragraphs.

Methods for Assessment of Specific Areas

After identifying the PCEs, the geographical area occupied, and the specific areas, the CHRT scored and rated the relative conservation value of each occupied specific area. The conservation value ratings provided an assessment of the relative importance of each specific area to the conservation of the Southern DPS. Areas rated as ''High'' were deemed to have a high likelihood of promoting the conservation of the Southern DPS. Areas rated as ''Medium'' or ''Low'' were deemed to have a moderate or low likelihood of promoting the conservation of the Southern DPS, respectively. The CHRT considered several factors in assigning the conservation value ratings, including the PCEs present, the condition of the PCEs, the life stages and habitat functions supported, and the historical, present, and potential future use of the area by green sturgeon. These factors were scored by the CHRT and summed to generate a total score for each specific area, which was considered in the CHRT's evaluation and assignment of the final conservation value ratings.

The CHRT also considered the importance of connectivity among habitats, recognizing that green sturgeon must migrate along the coast to access important oversummering and overwintering habitats in coastal bays and estuaries. Specific areas in coastal marine waters may provide low to medium value habitat for green sturgeon based on the PCEs present. However, such areas may contain high-value connectivity corridors for green sturgeon migrating out of the San Francisco Bay system to bays and estuaries in California, Oregon, Washington, and Canada, without which green sturgeon would not be able to access high-value habitats. The CHRT recognized that even within an area of Low to Medium conservation value, the presence of a migratory/connectivity corridor that provides passage to high value areas would warrant increasing the overall conservation value of the area to a High. To account for this, a separate conservation value rating was assigned to areas containing a migratory/connectivity corridor, equal to the rating of the highest-rated area for which it served as a migratory/connectivity corridor.

Members of the CHRT were then asked to re-examine the conservation value ratings for the specific areas where the presence of Southern DPS green sturgeon is likely (based on the presence of Northern DPS fish or green sturgeon of unknown origin), but not confirmed. These areas include the coastal marine waters within 110 m depth from the California/Mexico border to Monterey Bay, CA, and from Yakutat Bay, AK, to the Bering Strait (including the Bering Sea), as well as the following coastal bays and estuaries: Elkhorn Slough, CA; Tomales Bay, CA; Noyo Harbor, CA; Eel River estuary, CA; Klamath/Trinity River estuary, CA; Rogue River estuary, OR; Siuslaw River estuary, OR; Alsea River estuary, OR; Yaquina Bay, OR; and Tillamook Bay, OR. While these areas are considered occupied for the reasons provided above, the CHRT recognized that a lack of documented evidence for Southern DPS presence within these areas (perhaps because of the lack of monitoring or sampling effort within these areas) is indicative of a high degree of uncertainty as to the extent to which Southern DPS fish use these areas. The low occurrence of green sturgeon within these areas is also indicated by few observations of the species in these areas, both historically and recently. The CHRT scored all of these areas, except for Tomales Bay, CA, much lower than other areas, reflecting the CHRT's assessment that these areas contribute relatively little to the conservation of the species. For the bays and estuaries, this was based on the limited area and depth to support green sturgeon migration and feeding, as well as the low use of these areas by green sturgeon. Tomales Bay, CA, was given a higher score and rated as ''Medium,'' because it is a large, deep embayment providing good habitat for feeding by green sturgeon and is likely the first major bay to be encountered by subadults making their first migration into marine waters. As described above (see ''Bays and Estuaries''), green sturgeon are more commonly observed in the Eel River estuary, Klamath/Trinity River estuary, and Rogue River estuary, but are believed to primarily belong to the Northern DPS. Again, there is great uncertainty as to the extent of use of these estuaries by Southern DPS fish. For the coastal marine waters, the two areas are outside of the migratory/connectivity corridor identified by the CHRT and also lack confirmed Southern DPS presence. Although the CHRT did not include the area in southeast Alaska up to Yakutat Bay, AK, as part of the primary migratory corridor, this area was rated as ''Medium'' because it represents the northern extent of the area containing important overwintering grounds for Southern DPS green sturgeon (Lindley *et al.,* 2008; S. Lindley and M. Moser, NMFS, 2008, unpublished data). Based on this information, the CHRT agreed that the conservation value ratings should be reduced by one rating for these specific areas where the presence of the Southern DPS is likely, but not confirmed. This necessitated the creation of a fourth conservation value rating (''Ultra-low''). Those specific areas that initially received a ''Low'' rating were assigned a final conservation value rating of ''Ultra-low,'' whereas those areas that initially received a ''Medium'' rating were assigned a final conservation value rating of ''Low.'' None of the specific areas where the presence of Southern DPS fish was likely but not confirmed had received a rating of ''High.''

The final conservation ratings and the justifications for each specific area are summarized in the draft biological report (available via our Web site at *http://swr.nmfs.noaa.gov,* via the Federal eRulemaking Web site at *http://www.regulations.gov,* or upon

request—see **ADDRESSES**). The CHRT recognized that even within a rating category, variation exists. For example, freshwater riverine areas rated as ''High'' may be of greater conservation value to the species than coastal marine areas with the same rating. This variation was captured in the comments provided by the CHRT members for each specific area. The draft biological report describes in detail the evaluation process used by the CHRT to assess the specific areas, as well as the biological information supporting the CHRT's assessment.

Determining the Benefits of Excluding Particular Areas

To determine the benefits of excluding particular areas from designation, we considered the Federal activities that may be subject to an ESA section 7 consultation and the range of potential changes that may be required for each of these activities under the adverse modification provision, regardless of whether those changes may also be required under the jeopardy provision. These consultation and project modification costs represent the economic benefits of excluding each particular area (that is, the economic costs that would be avoided if an area were excluded from the designation).

The CHRT identified and examined the types of Federal activities that occur within each of the specific areas and that may affect Southern DPS green sturgeon and the critical habitat (also see the section on ''Special Management Considerations or Protection''). Because the Southern DPS was recently listed under the ESA in 2006, we lack an extensive consultation history. Thus, the CHRT relied on NMFS' experience in conducting ESA section 7 consultations and their best professional judgment to identify the types of Federal activities that might trigger a section 7 consultation. These include: (1) The installation and operation of dams; (2) the installation and operation of water diversions; (3) in-water construction or alterations; (4) dredging operations and disposal of dredge material; (5) NPDES permit activities and activities generating non-point source pollution, such as agricultural runoff; (6) power plant operations; (7) operations of liquefied natural gas (LNG) projects; (8) discharges from desalination plants; (9) commercial shipping (*e.g.,* discharges, oil spills); (10) aquaculture; (11) tidal or wave energy projects; (12) bottom trawl fisheries; and (13) habitat restoration. While we relied on the best, currently available information to predict the number of these types of activities within the areas considered for designation as critical habitat, we recognize that some of these activities, in particular tidal or wave energy projects, are relatively new and anticipated to increase in number in the future. Relevant information received during the comment period on the number and nature of such projects expected to occur within the proposed critical habitat will inform any final designation of critical habitat. In addition, relevant information concerning the potential impacts to activities, particularly LNG and hydropower activities, will also inform any final designation, including our determinations of whether to exclude any particular area from the designation.

We then considered the range of modifications we might seek in these activities to avoid destroying or adversely modifying critical habitat of the Southern DPS. Because of the limited consultation history, we relied on information from consultations conducted for salmon and steelhead, comments received during green sturgeon public scoping workshops conducted for the development of protective regulations, and information from green sturgeon and section 7 biologists to determine the types of activities and potential range of changes. While we recognize that differences between the biology of Southern DPS green sturgeon and listed salmonids exist, there is also overlap in the types of habitat they use, their life history strategies and their behavior. Given the limited amount of direct information regarding the types of modifications we might seek to avoid adverse modification of Southern DPS critical habitat, we relied on the best information available for analog species (*i.e.,* the listed salmonids) to guide our decision making. Additional information on differences in the habitat needs, life history strategies, and behavior of these species may allow us to refine our analysis. For each potential impact, we tried to provide information on whether the impact is more closely associated with adverse modification or with jeopardy, to distinguish the impacts of applying the jeopardy provision versus the adverse modification provision.

We were able to monetize estimates of the economic impacts resulting from a critical habitat designation; however, because of the limited consultation history for green sturgeon and uncertainty about specific management actions likely to be required under a consultation, there was a great degree of uncertainty in the cost estimates for some specific areas. Several factors were considered in developing the estimated economic impacts, including the level of economic activity within each area, the level of baseline protection afforded to green sturgeon by existing regulations for each economic activity within each area, and the estimated economic impact (in dollars) associated with each activity type. The baseline included the protections afforded to green sturgeon by the listing and jeopardy provision, as well as protections provided for salmon and steelhead and their critical habitat including existing laws, regulations, and initiatives. Estimates of the economic costs were based on project modifications that might be required during consultation to avoid the destruction or adverse modification of critical habitat (see draft Economic Analysis Report for additional details). Thus, the estimated economic impacts represent the incremental impact of the designation. The draft economic analysis sets forth detailed information on the economic impacts of designating particular areas as critical habitat, as well as consultation costs anticipated as a result of this proposed designation.

Our determination of these incremental economic impacts was based on the best available information. We solicit comment on the incremental values assigned in the economic report and will consider any relevant information received, including relevant differences in the biology of listed salmonids and green sturgeon, in developing the economic analysis supporting any final designation.

Exclusions Based on Economic Impacts

A draft ESA 4(b)(2) report describes in detail our approach to weighing the benefit of designation against the economic benefit of exclusion. The results of our analysis contained in this report are summarized below.

The benefits associated with species conservation are not directly comparable to the economic benefit, benefit to national security, or other relevant benefit that would result if an area were excluded from designation. We had sufficient information to monetize the economic benefits of excluding an area, but were not able to monetize the conservation benefits of designating an area. Thus, for each area we compared the qualitative conservation value against the monetary economic impact estimate to determine if the cost estimate exceeded a threshold dollar amount. Areas where the economic benefit of exclusion outweighed the benefit of designation were considered for exclusion from designation as critical habitat.

We identified areas eligible for exclusion based on four decision rules: (1) All areas with a conservation value rating of ''High'' were not eligible for exclusion regardless of the level of economic impact, because of the threatened status of the Southern DPS of green sturgeon; (2) areas with a conservation value rating of ''Medium'' were eligible for exclusion if the estimated economic impact exceeded $100,000; (3) areas with a conservation value rating of ''Low'' were eligible for exclusion if the estimated economic impact exceeded $10,000; and (4) areas with a conservation value rating of ''Ultra-low'' were eligible for exclusion if the estimated economic impact exceeded $0 (see draft 4(b)(2) Report for additional details). These dollar thresholds do not represent an objective judgment that Medium-value areas are worth no more than $100,000, Low-value areas are worth no more than $10,000, or Ultra-Low value areas are worth $0. Under the ESA, we are to weigh dissimilar impacts given limited time and information. The statute emphasizes that the decision to exclude is discretionary. Thus, the economic impact level at which the economic benefits of exclusion outweigh the conservation benefits of designation is a matter of discretion and depends on the policy context. For critical habitat, the ESA directs us to consider exclusions to avoid high economic impacts, but also requires that the areas designated as critical habitat are sufficient to support the conservation of the species and to avoid extinction. In this policy context, we selected dollar thresholds representing the levels at which the economic impact associated with a specific area would outweigh the conservation benefits of designating that area. These dollar thresholds and decision rules provided a relatively simple process to identify, in a limited amount of time, specific areas warranting consideration for exclusion.

Based on this analysis, we identified 15 occupied areas as eligible for exclusion: (1) Elkhorn Slough, CA; (2) the lower Feather River, CA; (3) Tomales Bay, CA; (4) Noyo Harbor, CA; (5) Eel River estuary, CA; (6) Klamath/Trinity River estuary, CA; (7) Rogue River estuary, OR; (8) Coos Bay, OR; (9) Siuslaw River estuary, OR; (10) Alsea River estuary, OR; (11) Tillamook Bay, OR; (12) Puget Sound, WA; (13) coastal marine waters within 110 m depth from the CA-Mexico border to Monterey Bay, CA; (14) coastal marine waters within 110 m depth from the Alaska/Canada border to Yakutat Bay, AK; and (15) coastal marine waters within 110 m depth northwest of Yakutat Bay, AK, to the Bering Strait (including the Bering Sea).

We asked the CHRT whether excluding any of the areas eligible for exclusion would significantly impede conservation of the Southern DPS or result in extinction of the species. The CHRT considered these questions in the context of all of the areas eligible for exclusion, as well as the information they had developed in determining the conservation value ratings.

The CHRT determined, and we concur, that exclusion of the following 11 areas eligible for exclusion would not significantly impede conservation or result in extinction of the species: (1) Elkhorn Slough, CA; (2) Tomales Bay, CA; (3) Noyo Harbor, CA; (4) Eel River estuary, CA; (5) Klamath/Trinity River estuary, CA; (6) Rogue River estuary, OR; (7) Siuslaw River estuary, OR; (8) Alsea River estuary, OR; (9) Tillamook Bay, OR; (10) coastal marine waters within 110 m depth from the California/Mexico border to Monterey Bay, CA; and (11) coastal marine waters within 110 m depth northwest of Yakutat Bay, AK, to the Bering Strait (including the Bering Sea). The CHRT based their determination on the fact that each of these 11 areas was assigned a Low or Ultra-low conservation value and Southern DPS fish have not been documented to use these areas extensively. The CHRT discussed the fact that the bays and estuaries eligible for exclusion listed above may not be used often by the Southern DPS because: (1) They are relatively small systems compared to other bays and estuaries that are used extensively and consequently received higher conservation ratings; and (2) Southern DPS fish do not appear to use Northern DPS spawning systems extensively. The CHRT discussed the fact that few green sturgeon (of unknown DPS) have been observed in coastal marine waters within 110 m depth from the California/Mexico border to Monterey Bay, CA; and northwest of Yakutat Bay, AK, to the Bering Strait (including the Bering Sea). For these reasons, the CHRT concluded that excluding the bays, estuaries and coastal marine areas mentioned above from the designation would not significantly impede conservation of the Southern DPS nor result in extinction of the species. Thus, we propose to exclude these 11 areas from the critical habitat designation for the Southern DPS. We recognize that the lack of documented evidence for Southern DPS presence in these areas may be because these areas are not adequately monitored for green sturgeon. We would encourage directed surveys to be conducted in these areas.

The CHRT also reevaluated the four areas of medium conservation value that were eligible for exclusion (lower Feather River, CA; Coos Bay, OR; Puget Sound, WA; and coastal marine waters within 110 m depth from the Alaska/Canada border to Yakutat Bay, AK) to determine whether excluding them would significantly impede conservation of the Southern DPS or result in extinction of the species. The CHRT determined that exclusion of Puget Sound would not significantly impede conservation of the Southern DPS. Observations of green sturgeon in Puget Sound are much less common compared to the other estuaries in Washington. Although two confirmed Southern DPS fish were detected there in 2006, the extent to which Southern DPS green sturgeon use Puget Sound remains uncertain. Despite the fact that Puget Sound has a long history of commercial and recreational fishing and fishery-independent monitoring of other species that use habitats similar to those of green sturgeon, very few green sturgeon have been observed there. In addition, Puget Sound does not appear to be part of the coastal migratory corridor that Southern DPS fish use to reach overwintering grounds north of Vancouver Island (S. Lindley and M. Moser, NMFS, 2008, pers. comm.), thus corroborating the assertion that Southern DPS do not use Puget Sound extensively. The economic cost of designating this area was well above the $100 K threshold because of the large number of activities affecting sediment and water quality (*i.e.*, dredging, in-water construction, and point and non-point sources of pollution) that might require special management if critical habitat were to be designated. Thus, we propose to exclude Puget Sound as critical habitat for the Southern DPS, because the benefits of designation are outweighed by the benefits of exclusion, and because the exclusion of this area will not result in the extinction of the species.

The CHRT unanimously agreed that exclusion of the lower Feather River would significantly impede conservation of the Southern DPS. The CHRT identified the lower Feather River as an important area for the conservation of the Southern DPS, because it has been consistently occupied by the species and most likely contains spawning habitat for the Southern DPS, potentially providing a spawning river for the Southern DPS in addition to the Sacramento River. The CHRT had assigned the lower Feather River a Medium conservation value, but

noted that future improvements to habitat conditions (*e.g.*, improved passage, restoration of water flow) are both logistically and financially feasible and if they were carried out, would raise the conservation value to a High. We propose to designate the lower Feather River as critical habitat for the Southern DPS to protect the high conservation potential of this area and reduce extinction risk. We solicit additional data and comments from the public regarding designation of the Lower Feather River, particularly information regarding the economic costs associated with activities that may be affected by a critical habitat designation and on the conservation benefits to green sturgeon provided by this area.

The CHRT also determined that exclusion of Coos Bay would significantly impede the conservation of the species. The CHRT identified Coos Bay as an important area for the Southern DPS because it is the largest and deepest estuary along the Oregon coast presently occupied by green sturgeon, has a large mixing zone, provides a protected area for green sturgeon aggregation and feeding, and is an important ''stepping-stone'' estuary between San Francisco Bay and the lower Columbia River estuary. There is a great degree of uncertainty regarding the economic costs associated with a designation in this area. The estimated costs ranged from $19,000 to $16 million, spanning the threshold value over which an area was considered eligible for exclusion ($100,000 for areas with a Medium conservation value). This uncertainty was driven largely by the possible placement of one LNG terminal inside the bay, a limited understanding of how LNG projects would affect the PCEs, and uncertainty regarding how LNG activities might be altered to avoid adverse modification of green sturgeon critical habitat. Because there is great uncertainty regarding the LNG project at this time, we considered the lower economic impact estimate ($19,000) in developing this proposed rule. Based on this information, we propose to designate Coos Bay as critical habitat for the Southern DPS, because the conservation value of the area outweighs what we consider to be the more realistic economic cost of designation (*i.e.,* approximately $19,000). At this time, we propose that designating critical habitat in Coos Bay will provide conservation value to the species and reduce extinction risk. However, we acknowledge that $19,000 is likely a low estimate of the impact likely to occur as a result of this proposed critical habitat designation. During the comment period we seek from the public and will request from relevant Federal agencies additional data and information, in particular information regarding additional costs incurred by the LNG industry, to develop a more accurate assessment of the likely costs of this proposed designation in Coos Bay and other areas in the lower Columbia River estuary. We will use such information in our economic analysis and ESA 4(b)(2) weighing process such that a reconsideration of the proposed designation of Coos Bay and other areas along the lower Columbia River estuary may be warranted. Therefore, we solicit additional data and comments regarding designation of Coos Bay and other areas along the lower Columbia River estuary, particularly information regarding the economic costs associated with LNG projects that may occur as a result of a critical habitat designation.

The CHRT also looked closely at the possible exclusion of the coastal marine waters within 110 m depth from the Alaska/Canada border to Yakutat Bay, AK. Some CHRT members noted that the exclusion of this area from the designation might impede conservation of the Southern DPS, because this area may be an important component of the overwintering range for the species. Although only two tagged Southern DPS green sturgeon have been detected in this area, the fact that the detection system in Graves Harbor, AK, is not designed to detect green sturgeon and that the data have only been collected from 2005–2006 suggests that Southern DPS use of the area may be greater than indicated by the available data. Other CHRT members stated that the relatively low number of Southern DPS detections in the area, in combination with the uncertainty surrounding the activities occurring in southeast Alaska, suggests that excluding this area from the designation would not significantly impede conservation or result in the extinction of the species. At this time, we propose to exclude the coastal marine waters within 110 m depth from the Alaska/Canada border to Yakutat Bay, AK, from the designation because the economic impacts outweigh the conservation benefit of designation in this area. We solicit the public for more information regarding: (1) The presence of green sturgeon in coastal waters off southeast Alaska; (2) the spatial distribution of the PCEs in southeast Alaska; (3) activities occurring in the area that may affect the PCEs; (4) the types of changes that might be proposed for these activities to avoid impacts to the PCEs; and (5) estimated costs associated with making these changes.

In summary, we propose to exclude the following 13 specific areas from the critical habitat designation: (1) Elkhorn Slough, CA; (2) Tomales Bay, CA; (3) Noyo Harbor, CA; (4) Eel River estuary, CA; (5) Klamath/Trinity River estuary, CA; (6) Rogue River estuary, OR; (7) Siuslaw River estuary, OR; (8) Alsea River estuary, OR; (9) Tillamook Bay, OR; (10) Puget Sound, WA; (11) coastal marine waters within 110 m depth from the California/Mexico border to Monterey Bay, CA; (12) coastal marine waters within 110 m depth from the Alaska/Canada border to Yakutat Bay, AK; and (13) coastal marine waters within 110 m depth northwest of Yakutat Bay, AK, to the Bering Strait (including the Bering Sea). Based on the best scientific and commercial data available, we have determined that the exclusion of these 13 areas from the designation would not result in the extinction of the species.

Exclusions Based on Impacts on National Security

We have contacted the DOD regarding any DOD lands that may overlap with areas proposed for designation as critical habitat for the Southern DPS. At this time, we have not received information identifying impacts on national security that may result from the designation. However, we solicit comments from the public and from the DOD regarding any national security concerns for the areas proposed for designation. We are aware of DOD sites in the Strait of Juan de Fuca that have been excluded on the basis of national security impacts for Southern Resident killer whales and Puget Sound salmon, as well as DOD sites off the coasts of California and Washington that may be affected by a critical habitat designation. We request information specifically pertaining to whether the designation for such sites as critical habitat for the Southern DPS would result in national security impacts that would outweigh the benefits of designation.

Other Relevant Impacts

We did not propose exclusions based on other relevant impacts of designation, particularly impacts on Indian tribes.

For this proposed critical habitat designation for Southern DPS green sturgeon, we reviewed maps indicating that very few if any areas under consideration as critical habitat actually overlap with Indian lands. Nearshore coastal areas comprise the vast majority of these possible overlap areas, but it is unclear which if any Indian lands are

subject to consideration for possible exclusion. In particular, we lack information regarding where Indian land boundaries lie in relation to shoreline tidal boundaries used to identify the lateral extent in this proposed rule. Our preliminary assessment indicates that the following federally-recognized tribes (73 FR 18553, April 4, 2008) have lands that may be in close proximity to areas under consideration for designation as critical habitat for Southern DPS green sturgeon: the Hoh, Jamestown S'Klallam, Lower Elwha, Makah, Quileute, Quinault, and Shoalwater Bay tribes in Washington; the Confederated Tribes of Coos Lower Umpqua and Siuslaw Indians and the Coquille Tribe in Oregon; and the Cachil DeHe Band of Wintun Indians of the Colusa Indian Community, Wiyot Tribe, and Yurok Tribe in California.

We seek comments regarding these areas and will continue to investigate whether any Indian lands overlap, and may warrant exclusion from, critical habitat for Southern DPS green sturgeon. Indian lands are those defined in the Secretarial Order ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997), including: (1) Lands held in trust by the United States for the benefit of any Indian tribe; (2) land held in trust by the United States for any Indian Tribe or individual subject to restrictions by the United States against alienation; (3) fee lands, either within or outside the reservation boundaries, owned by the tribal government; and (4) fee lands within the reservation boundaries owned by individual Indians.

If such areas are identified, the benefits of exclusion could include those we identified in recent critical habitat designations for Pacific salmon and steelhead (70 FR 52630; September 2, 2005), specifically: (1) The furtherance of established national policies, our Federal trust obligations and our deference to the tribes in management of natural resources on their lands; (2) the maintenance of effective long-term working relationships to promote species conservation on an ecosystem-wide basis; (3) the allowance for continued meaningful collaboration and cooperation in scientific work to learn more about the conservation needs of the species on an ecosystem-wide basis; and (4) continued respect for tribal sovereignty over management of natural resources on Indian lands through established tribal natural resource programs.

We also seek information from affected tribes concerning other tribal activities that may be affected in areas other than tribal lands (*i.e.*, bottom trawling and alternative energy projects in marine areas).

Critical Habitat Designation

We propose to designate approximately 325 miles (524 km) of riverine habitat and 1,058 square miles (2,739 sq km) of estuarine habitat in California, Oregon, and Washington, and 11,927 square miles (30,890 sq km) of coastal marine habitat off California, Oregon, and Washington within the geographical area presently occupied by the Southern DPS of green sturgeon. We also propose to designate approximately 136 square miles (352 sq km) of habitat within the Yolo and Sutter bypasses, adjacent to the Sacramento River, California. The proposed critical habitat areas contain physical or biological features essential to the conservation of the species that may require special management considerations or protection. We propose to exclude 13 areas from designation for which the benefit of exclusion outweighing the benefit of inclusion. We conclude that the exclusion of these areas will not result in the extinction of the Southern DPS. Although we have identified 7 presently unoccupied areas that may be later determined to be essential to conservation, we are not proposing any unoccupied areas for designation as critical habitat at this time, because we do not have sufficient information to determine that any of the unoccupied areas are essential to the conservation of the species.

Lateral Extent of Critical Habitat

For freshwater riverine habitats, we described the lateral extent of critical habitat units as the width of the stream channel defined by the ordinary high-water line, as defined by the U.S. Army Corps of Engineers (COE) in 33 CFR 329.11. The ordinary high-water line on non-tidal rivers is defined as ''the line on the shore established by the fluctuations of water and indicated by physical characteristics such as a clear, natural line impressed on the bank; shelving; changes in the character of soil; destruction of terrestrial vegetation; the presence of litter and debris, or other appropriate means that consider the characteristics of the surrounding areas'' (33 CFR 329.11(a)(1)). In areas for which the ordinary high-water line has not been defined pursuant to 33 CFR 329.11, we defined the width of the stream channel by its bankfull elevation. Bankfull elevation is the level at which water begins to leave the channel and move into the floodplain (Rosgen, 1996) and is reached at a discharge which generally has a recurrence interval of 1 to 2 years on the annual flood series (Leopold *et al.*, 1992). For bays and estuarine areas, we defined the lateral extent by the mean higher high water (MHHW) line. For coastal marine habitats, the lateral extent to the west is defined by the 110 m depth bathymetry contour relative to the line of mean lower low water (MLLW) and shoreward to the area that is inundated by extreme high tide, or to the COLREGS demarcation lines delineating the boundary between estuarine and marine habitats. The textual descriptions of critical habitat in the section titled ''*226.215 Critical habitat for the Southern Distinct Population Segment of North American Green Sturgeon (Acipenser medirostris)*'' are the definitive source for determining the critical habitat boundaries. The overview maps provided in section ''*226.215 Critical habitat for the Southern Distinct Population Segment of North American Green Sturgeon (Acipenser medirostris)*'' are provided for general guidance purposes only and not as a definitive source for determining critical habitat boundaries.

As discussed in previous critical habitat designations, the quality of aquatic and estuarine habitats within stream channels and bays and estuaries is intrinsically related to the adjacent riparian zones and floodplain, to surrounding wetlands and uplands, and to non-fish-bearing streams above occupied stream reaches. Human activities that occur outside of designated streams, bays, or estuaries can destroy or adversely modify the essential physical and biological features within these areas. In addition, human activities occurring within and adjacent to reaches upstream or downstream of designated stream reaches or estuaries can also destroy or adversely modify the essential physical and biological features of these areas. Similarly, human activities that occur outside of designated coastal marine areas inundated by extreme high tide can destroy or adversely modify the essential physical and biological features of these areas. This designation will help to ensure that Federal agencies are aware of these important habitat linkages.

Effects of Critical Habitat Designation

ESA Section 7 Consultation

Section 7(a)(2) of the ESA requires Federal agencies, including NMFS, to insure that any action authorized, funded, or carried out by the agency

(agency action) does not jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat.

Federal agencies are also required to confer with NMFS regarding any actions likely to jeopardize a species proposed for listing under the ESA, or likely to destroy or adversely modify proposed critical habitat, pursuant to section 7(a)(4). A conference involves informal discussions in which NMFS may recommend conservation measures to minimize or avoid adverse effects. The discussions and conservation recommendations are to be documented in a conference report provided to the Federal agency. If requested by the Federal agency, a formal conference report may be issued, including a biological opinion prepared according to 50 CFR 402.14. A formal conference report may be adopted as the biological opinion when the species is listed or critical habitat designated, if no significant new information or changes to the action alter the content of the opinion.

When a species is listed or critical habitat is designated, Federal agencies must consult with NMFS on any agency actions to be conducted in an area where the species is present and that may affect the species or its critical habitat. During the consultation, NMFS would evaluate the agency action to determine whether the action may adversely affect listed species or critical habitat and issue its findings in a biological opinion. If NMFS concludes in the biological opinion that the agency action would likely result in the destruction or adverse modification of critical habitat, NMFS would also recommend any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives are defined in 50 CFR 402.02 as alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinitiate consultation on previously reviewed actions in instances where: (1) Critical habitat is subsequently designated; or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of consultation or conference with NMFS on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

Activities subject to the ESA section 7 consultation process include activities on Federal lands and activities on private or state lands requiring a permit from a Federal agency (*e.g.*, a section 10(a)(1)(B) permit from NMFS) or some other Federal action, including funding (*e.g.*, Federal Highway Administration (FHA) or Federal Emergency Management Agency (FEMA) funding). ESA section 7 consultation would not be required for Federal actions that do not affect listed species or critical habitat and for actions on non-Federal and private lands that are not Federally funded, authorized, or carried out.

Activities Likely To Be Affected

ESA section 4(b)(8) requires in any proposed or final regulation to designate critical habitat an evaluation and brief description of those activities (whether public or private) that may adversely modify such habitat or that may be affected by such designation. A wide variety of activities may affect the proposed critical habitat and may be subject to the ESA section 7 consultation process when carried out, funded, or authorized by a Federal agency. These include water and land management actions of Federal agencies (*e.g.*, U.S. Forest Service (USFS), Bureau of Land Management (BLM), Army Corps of Engineers (COE), U.S. Bureau of Reclamation (BOR), Natural Resource Conservation Service (NRCS), National Park Service (NPS), Bureau of Indian Affairs (BIA), the Federal Energy Regulatory Commission (FERC), and the Nuclear Regulatory Commission (NRC)) and related or similar Federally-regulated projects and activities Federal lands, including hydropower sites and proposed tidal/wave energy projects licensed by the FERC; nuclear power sites licensed by the NRC; dams built or operated by the COE or BOR; timber sales and other vegetation management activities conducted by the USFS, BLM and BIA; irrigation diversions authorized by the USFS and BLM; and road building and maintenance activities authorized by the USFS, BLM, NPA, and BIA. Other actions of concern include dredge and fill, mining, diking, and bank stabilization activities authorized or conducted by the COE, habitat modifications authorized by the FEMA, and approval of water quality standards and pesticide labeling and use restrictions administered by the Environmental Protection Agency (EPA).

Private entities may also be affected by this proposed critical habitat designation if a Federal permit is required, Federal funding is received, or the entity is involved in or receives benefits from a Federal project. For example, private entities may have special use permits to convey water or build access roads across Federal land; they may require Federal permits to construct irrigation withdrawal facilities, or build or repair docks; they may obtain water from Federally funded and operated irrigation projects; or they may apply pesticides that are only available with Federal agency approval. These activities will need to be evaluated with respect to their potential to destroy or adversely modify critical habitat. Changes to the actions to minimize or avoid destruction or adverse modification of proposed critical habitat may result in changes to some activities, such as the operations of dams and dredging activities. Transportation and utilities sectors may need to modify the placement of culverts, bridges, and utility conveyances (*e.g.*, water, sewer, and power lines) to avoid barriers to fish migration. Developments (*e.g.*, marinas, residential, or industrial facilities) occurring in or near streams, estuaries, or marine waters designated as critical habitat that require Federal authorization or funding may need to be altered or built in a manner to ensure that critical habitat is not destroyed or adversely modified as a result of the construction or subsequent operation of the facility.

Questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat should be directed to NMFS (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Public Comments Solicited

To ensure the final action resulting from this proposal will be as accurate and as effective as possible, we solicit comments and suggestions from the public, other concerned governments and agencies, the scientific community, industry, or any other interested party concerning this proposed rule. Specifically, public comments are sought concerning: (1) Information describing the abundance, distribution, and habitat use of Southern DPS green sturgeon in freshwater rivers, bays, estuaries, and coastal marine waters; (2)

Information on the identification, location, and quality of physical or biological features which may be essential to the conservation of the Southern DPS; (3) Information regarding potential impacts of designating any particular area, including the types of Federal activities that may trigger an ESA section 7 consultation and the possible modifications that may be required of those activities as a result of section 7 consultation; (4) Information regarding the benefits of designating any particular area of the proposed critical habitat; (5) Information regarding the benefits of excluding particular areas from the critical habitat designation; (6) Current or planned activities in the areas proposed for designation and their possible impacts on proposed critical habitat; and (7) Any foreseeable economic, national security, or other relevant impacts resulting from the proposed designations.

We encourage comments on this proposal. You may submit your comments and materials by any one of several methods (see **ADDRESSES**). The proposed rule, maps, references, and other materials relating to this proposal can be found on our Web site at *http://swr.nmfs.noaa.gov*. We will consider all comments and information received during the comment period for this proposed rule in preparing the final rule.

Public Hearings

Regulations at 50 CFR 424.16(c)(3) require the Secretary to promptly hold at least one public hearing if any person requests one within 45 days of publication of a proposed rule to designate critical habitat. Requests for a public hearing must be made in writing (see **ADDRESSES**) by October 23, 2008. If a public hearing is requested, a notice detailing the specific hearing location and time will be published in the **Federal Register** at least 15 days before the hearing is to be held. Information on specific hearing locations and times will also be posted on our Web site at *http://swr.nmfs.noaa.gov*. These hearings provide the opportunity for interested individuals and parties to give comments, exchange information and opinions, and engage in a constructive dialogue concerning this proposed rule. We encourage the public's involvement in such ESA matters.

Peer Review

On July 1, 1994, a joint USFWS/NMFS policy for peer review was issued stating that the Services would solicit independent peer review to ensure the best biological and commercial data is used in the development of rulemaking actions and draft recovery plans under the ESA (59 FR 34270). On December 16, 2004, the Office of Management and Budget (OMB) issued its Final Information Quality Bulletin for Peer Review (Bulletin). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664), and went into effect on June 16, 2005. The primary purpose of the Bulletin is to improve the quality and credibility of scientific information disseminated by the Federal government by requiring peer review of ''influential scientific information'' and highly influential scientific information'' prior to public dissemination. Influential scientific information is defined as ''information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' The Bulletin provides agencies broad discretion in determining the appropriate process and level of peer review. Stricter standards were established for the peer review of ''highly influential scientific assessments,'' defined as information whose ''dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.'' Two documents supporting this proposal to designate critical habitat for the Southern DPS of green sturgeon are considered influential scientific information and subject to peer review. These documents are the draft Biological Report and draft Economic Analysis. We have distributed the draft Biological Report and draft Economic Analysis for independent peer review and will address any comments received in developing the final drafts of the two reports. Both documents are available on our Web site at *http://swr.nmfs.noaa.gov*, on the Federal eRulemaking Web site at *http://www.regulations.gov*, or upon request (see **ADDRESSES**).

Required Determinations

Clarity of the Rule

Section I(12) of Executive Order (E.O.) 12866 requires each agency to write regulations and notices that are easy to understand. NMFS invites your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the rule? (6) What else could NMFS do to make the rule easier to understand? You may submit comments on how we could make this proposed rule easier to understand by any one of several methods (see **ADDRESSES**).

Regulatory Planning and Review (E.O. 12866)

This proposed rule has been determined to be significant for purposes of E.O. 12866. A draft economic report and ESA section 4(b)(2) report have been prepared to support the exclusion process under section 4(b)(2) of the ESA.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency publishes a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis describing the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). We have prepared an initial regulatory flexibility analysis (IRFA), which is part of the draft Economic Analysis. This document is available upon request (see **ADDRESSES**), via our Web site at *http://swr.nmfs.noaa.gov*, or via the Federal eRulemaking Web site at *http://www.regulations.gov*. The results of the IRFA are summarized below.

At the present time, little information exists regarding the cost structure and operational procedures and strategies in the sectors that may be directly affected by the potential critical habitat designation. In addition, given the short consultation history for green sturgeon, there is significant uncertainty regarding the activities that may trigger an ESA section 7 consultation or how those activities may be modified as a result of consultation. With these limitations in mind, we considered which of the potential economic impacts we analyzed might affect small entities. These estimates should not be considered exact estimates of the impacts of potential critical habitat to individual businesses.

The impacts to small businesses were assessed for the following eight activities: dredging, in-water construction or alterations, NPDES activities and other activities resulting in non-point pollution, agriculture, dam operations, water diversion operations, bottom trawl fisheries, and power plant operations. The impacts on small entities were not assessed for LNG projects, desalination plants, tidal and wave energy projects, and restoration projects because there is great uncertainty regarding impacts to these activities, the activities are unlikely to be conducted by small entities, or the impacts to small businesses are expected to be minor.

Small entities were defined by the Small Business Administration size standards for each activity type. The majority (> 80 percent) of entities affected within each specific area would be considered a small entity. A total of 11,002 small businesses involved in the activities listed above would most likely be affected by the proposed critical habitat designation. The estimated annualized costs associated with section 7 consultations incurred per small entity range from $0 to $130,000, with the largest annualized impacts estimated for entities involved in bottom trawl fisheries ($10 to $130,000) and the operation of dams and water diversions ($0 to $89,000). The total estimated annualized costs of section 7 consultation incurred by small entities is estimated to range from $467,600 to $640,661 (the range is costs is due to varying costs associated with bottom trawl fisheries). The estimated economic impacts on small entities vary depending on the activity type and location.

As required by the RFA (as amended by the SBREFA), we considered various alternatives to the proposed critical habitat designation for the Southern DPS. We considered and rejected the alternative of not designating critical habitat for the Southern DPS because such an approach does not meet the legal requirements of the ESA. We also considered and rejected the alternative of proposing the designation of all potential critical habitat areas of the Southern DPS (*i.e.*, no areas are excluded), because for several areas, the economic benefits of exclusion outweighed the benefits of inclusion and we did not determine that exclusion of these areas would significantly impede conservation of the species or result in extinction of the species. We have considered and evaluated each of these alternatives in the context of the section 4(b)(2) process of weighing benefits of exclusion against benefits of designation, and determined that the current proposal provides an appropriate balance between conservation needs and the associated economic and other relevant impacts. It is estimated that small entities will save from $165,842 to $268,882 in compliance costs, due to the proposed exclusions made in this designation.

E.O. 13211

On May 18, 2001, the President issued an Executive Order on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking an action expected to lead to the promulgation of a final rule or regulation that is a significant regulatory action under E.O. 12866 and is likely to have a significant adverse effect on the supply, distribution, or use of energy.

We have considered the potential impacts of this action on the supply, distribution, or use of energy (see draft economic analysis report). Activities associated with the supply, distribution, or use of energy that may be affected by the critical habitat designation include the operation of: (1) Dams and dam facilities; (2) power plants; (3) proposed alternative energy projects; and (4) LNG projects.

All of the 189 dams analyzed in the economic analysis exist within the areas occupied by Southern DPS green sturgeon and may be affected by the potential critical habitat designation. The dams are located within the Central Valley, CA, and in the lower Columbia River estuary. Owners or operators of the dams may be required to undertake specific modifications to avoid destroying or adversely modifying the proposed critical habitat for green sturgeon. Given substantial variation in the potential for effects on green sturgeon and critical habitat, such modifications would be determined on a case-by-case basis, and costs would vary widely. Because the areas overlap with existing critical habitat designations for salmon species, and because the guidelines we have in place for dam modifications focus on listed salmonids, we will likely recommend modifications to dams that are similar to those we recommend for salmonids until additional information on green sturgeon indicates otherwise. Thus, the additional effects of the critical habitat designation for green sturgeon would likely be minimal. In addition, modifications required for the protection of critical habitat would likely be similar to those required under the jeopardy standard.

Of the 58 power plants analyzed in the economic analysis, approximately 56 power plants exist within the areas occupied by Southern DPS green sturgeon and may be affected by the potential critical habitat designation. The installation of new technology to cool thermal effluents may be required under an ESA section 7 consultation. All of the power plants except for one located on the California coast are subject to existing protections for salmon species. For similar reasons given in the previous paragraph, we would likely recommend modifications to power plants that are similar to those we recommend for protecting listed salmonid critical habitat until additional information indicates otherwise. For the one coastal power plant, modifications required for the protection of critical habitat would likely be similar to those required under the jeopardy standard.

Of the 36 alternative energy projects analyzed in the economic analysis, approximately 18 alternative energy projects have pending applications or have received preliminary permits to operate within bays, estuaries, and coastal marine waters proposed for designation as critical habitat for the Southern DPS of green sturgeon. Given the necessary timeframes for project construction, it may be reasonable to assume that this set of projects will incur project modification costs related to green sturgeon critical habitat within the next 20 years. However, it should also be noted that other new permit applications are likely to be filed in the future, and that rate of application may be increasing. The Federal Energy Regulatory Commission (FERC) points out that while it received only one application between 2004 and 2005 for hydrokinetic (tidal- and wave-energy) projects, it received seven preliminary permit applications in both 2006 and 2007 within the critical habitat study area, excluding Alaska waters. We seek comment on the likely number of projects within the timeframe of this analysis. Relevant information received will inform our final analysis.

Because these projects are in their preliminary stages, it is not clear what effects the projects will have on habitats and natural resources, nor what effects a critical habitat designation would have on these projects. Concerns over the entrainment or impingement of green sturgeon in structures associated with alternative energy projects would be addressed under the jeopardy standard, whereas impacts on passage and water quality would be addressed under the adverse modification provision. Such impacts are of concern

for other fish species as well as for green sturgeon (McIsaac, 2008, Letter from the Pacific Fishery Management Council to Randall Luthi, Minerals Management Service). It is likely that management measures to minimize or avoid habitat impacts for other species will be required for alternative energy projects. Based on the best available information, the project modifications we would require to protect green sturgeon critical habitat would likely be similar to those applied for the protection of other marine species.

Of the 12 LNG projects analyzed in the economic analysis, there are 4 proposed LNG projects within the areas proposed for designation as critical habitat, one within Coos Bay and three within the lower Columbia River. Like the alternative energy projects, there is a high degree of uncertainty regarding whether these proposed projects will be implemented. As a result, it is unclear at this time what effects a critical habitat designation would have on these proposed LNG projects. In cases where listed salmon and steelhead species or critical habitat designated for these species occurs within the areas where proposed LNG projects are located (*e.g.*, in the Lower Columbia River), the best available information indicates that measures implemented for the protection of these species would be similar to those required to protect critical habitat for green sturgeon. In areas where listed salmon and steelhead or critical habitat areas designated for these species are not present (*e.g.*, in Coos Bay, where critical habitat has not been designated for salmon and steelhead), measures implemented to avoid adverse modification of green sturgeon habitat may result in energy impacts.

Based on this preliminary analysis, we have initially determined that the designation of critical habitat for Southern DPS green sturgeon would not result in significant impacts on the supply, distribution, or use of energy.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act, NMFS makes the following findings:

(A) This proposed rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding'' and the State, local, or tribal government's ''lack authority'' to adjust accordingly. (At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement.) ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (I) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program.'' The designation of critical habitat does not impose an enforceable duty on non-Federal government entities or private parties. The only regulatory effect of a critical habitat designation is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under ESA section 7. Non-Federal entities who receive funding, assistance, or permits from Federal agencies, or otherwise require approval or authorization from a Federal agency for an action may be indirectly affected by the designation of critical habitat. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would critical habitat shift the costs of the large entitlement programs listed above to state governments.

(b) Due to the prohibition against take of the Southern DPS both within and outside of the designated areas, we do not anticipate that this proposed rule will significantly or uniquely affect small governments. As such, a Small Government Agency Plan is not required.

Takings

Under E.O. 12630, Federal agencies must consider the effects of their actions on constitutionally protected private property rights and avoid unnecessary takings of property. A taking of property includes actions that result in physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use. In accordance with E.O. 12630, this proposed rule does not have significant takings implications. A takings implication assessment is not required. The designation of critical habitat affects only Federal agency actions. This proposed rule would not increase or decrease the current restrictions on private property concerning take of Southern DPS fish, nor do we expect the proposed critical habitat designation to impose additional burdens on land use or affect property values. Additionally, the proposed critical habitat designation does not preclude the development of Habitat Conservation Plans and issuance of incidental take permits for non-Federal actions. Owners of areas included within the proposed critical habitat designation would continue to have the opportunity to use their property in ways consistent with the survival of listed Southern DPS.

Federalism

In accordance with E.O. 13132, we determined that this proposed rule does not have significant Federalism effects and that a Federalism assessment is not required. In keeping with Department of Commerce policies, we request information from, and will coordinate development of this proposed critical habitat designation with, appropriate state resource agencies in California, Oregon, Washington, and Alaska. The proposed designation may have some benefit to state and local resource agencies in that the areas essential to the conservation of the species are more clearly defined, and the PCEs of the habitat necessary for the survival of the Southern DPS of green sturgeon are specifically identified. While this designation does not alter where and what Federally sponsored activities may occur, it may assist local governments in long-range planning (rather than waiting for case-by-case ESA section 7 consultations to occur).

Civil Justice Reform

In accordance with E.O. 12988, we have determined that this proposed rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the E.O. We

are proposing to designate critical habitat in accordance with the provisions of the ESA. This proposed rule uses standard property descriptions and identifies the PCEs within the designated areas to assist the public in understanding the habitat needs of the Southern DPS of green sturgeon.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain new or revised information collections that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. This proposed rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

NMFS has determined that an environmental analysis as provided for under the NEPA of 1969 for critical habitat designations made pursuant to the ESA is not required. See *Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. Denied, 116 S.Ct 698 (1996).

Government-to-Government Relationship With Tribes

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal government. This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian Tribes and the application of fiduciary standards of due care with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities lands have been retained by Indian Tribes or have been set aside for tribal use. These lands are managed by Indian Tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. E.O. 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests.

There is a broad array of activities on Indian lands that may trigger ESA section 7 consultations. In the case of Southern DPS green sturgeon, we reviewed maps indicating that very few if any areas under consideration as critical habitat actually overlap with Indian lands. Nearshore coastal areas comprise the vast majority of these possible overlap areas, but it is unclear which if any Indian lands are subject to consideration for possible exclusion. In particular, we lack information regarding where Indian land boundaries lie in relation to shoreline tidal boundaries used to identify the lateral extent in this proposed rule. Our preliminary assessment indicates that the following federally recognized tribes (73 FR 18553, April 4, 2008) have lands that may be in close proximity to areas under consideration for designation as critical habitat for Southern DPS green sturgeon: The Hoh, Jamestown S'Klallam, Lower Elwha, Makah, Quileute, Quinault, and Shoalwater Bay tribes in Washington; the Confederated Tribes of Coos Lower Umpqua and Siuslaw Indians and the Coquille Tribe in Oregon; and the Cachil DeHe Band of Wintun Indians of the Colusa Indian Community, Wiyot Tribe, and Yurok Tribe in California.

We seek comments regarding these areas and will continue to investigate whether any Indian lands overlap, and may warrant exclusion from, critical habitat for Southern DPS green sturgeon. Indian lands are those defined in the Secretarial Order ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997), including: (1) Lands held in trust by the United States for the benefit of any Indian tribe; (2) land held in trust by the United States for any Indian Tribe or individual subject to restrictions by the United States against alienation; (3) fee lands, either within or outside the reservation boundaries, owned by the tribal government; and (4) fee lands within the reservation boundaries owned by individual Indians.

If such areas are identified, the benefits of exclusion could include those we identified in recent critical habitat designations for Pacific salmon and steelhead (70 FR 52630; September 2, 2005), specifically: (1) The furtherance of established national policies, our Federal trust obligations and our deference to the tribes in management of natural resources on their lands; (2) the maintenance of effective long-term working relationships to promote species conservation on an ecosystem-wide basis; (3) the allowance for continued meaningful collaboration and cooperation in scientific work to learn more about the conservation needs of the species on an ecosystem-wide basis; and (4) continued respect for tribal sovereignty over management of natural resources on Indian lands through established tribal natural resource programs.

We also seek information from affected tribes concerning other tribal activities that may be affected in areas other than tribal lands (*i.e.*, bottom trawling and alternative energy projects in marine areas).

References Cited

A complete list of all references cited herein is available upon request (see **ADDRESSES** section) or via our Web site at *http://swr.nmfs.noaa.gov.*

List of Subjects in 50 CFR Part 226

Endangered and threatened species.

Dated: August 29, 2008.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons set out in the preamble, we propose to amend part 226, title 50 of the Code of Federal Regulations as set forth below:

PART 226—DESIGNATED CRITICAL HABITAT

1. The authority citation of part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

2. Add § 226.216, to read as follows:

§ 226.216 Critical habitat for the Southern Distinct Population Segment of North American Green Sturgeon (Acipenser medirostris).

Critical habitat is designated for the Southern Distinct Population Segment of North American green sturgeon (Southern DPS) as described in this section. The textual descriptions of critical habitat in this section are the definitive source for determining the critical habitat boundaries. The overview maps are provided for general guidance purposes only and not as a definitive source for determining critical habitat boundaries.

(a) *Critical habitat boundaries.* Critical habitat in freshwater riverine areas includes the stream channels and a lateral extent as defined by the ordinary high-water line (33 CFR 329.11). In areas for which the ordinary high-water line has not been defined pursuant to 33 CFR 329.11, the lateral extent will be defined by the bankfull elevation. Bankfull elevation is the level at which water begins to leave the channel and move into the floodplain and is reached at a discharge which generally has a recurrence interval of 1

to 2 years on the annual flood series. Critical habitat in bays and estuaries includes tidally influenced areas as defined by the elevation of mean higher high water. The boundary between nearshore coastal marine areas and bays and estuaries are delineated by the COLREGS lines (33 CFR part 80). Critical habitat in coastal marine areas is defined by the zone between the 110 m depth bathymetry line and the line on shore reached by extreme high water, or to the COLREGS lines.

(1) *Coastal marine areas:* All U.S. coastal marine waters out to the 110 m depth bathymetry line (relative to MLLW) from Monterey Bay, California (36°38′12″ N./ 121°56′13″ W.) north and east to include waters in the Strait of Juan de Fuca, Washington. The Strait of Juan de Fuca includes all U.S. marine waters: In Clallam County east of a line connecting Cape Flattery (48°23′10″ N./ 124°43′32″ W.), Tatoosh Island (48°23′30″ N./ 124°44′12″ W.), and Bonilla Point, British Columbia (48°35′30″ N./ 124°43′00″ W.); in Jefferson and Island counties north and west of a line connecting Point Wilson (48°08′38″ N./ 122°45′07″ W.) and Admiralty Head (48°09′18″ N./ 122°40′41″ W.); and in San Juan and Skagit counties south of lines connecting the U.S.-Canada border (48°27′27″ N./ 123°09′46″ W.) and Pile Point (48°28′56″ N./ 123°05′33″ W.), Cattle Point (48°27′1″ N./ 122°57′39″ W.) and Davis Point (48°27′21″ N./ 122°56′03″ W.), and Fidalgo Head (48°29′34″ N./ 122°42′07″ W.) and Lopez Island (48°28′43″ N./ 122°49′08″ W.).

(2) *Freshwater riverine habitats:* Critical habitat is designated to include the following freshwater riverine areas in California:

(i) Sacramento River, California. From the Sacramento I-Street Bridge upstream to Keswick Dam (40°36′39″ N./ 122°26′41″ W.), including the waters encompassed by the Yolo Bypass and the Sutter Bypass areas.

(ii) Lower Feather River, California. From the confluence with the mainstem Sacramento River upstream to Oroville Dam (39°32′35″ N./ 121°29′27″ W.).

(iii) Lower Yuba River, California. From the confluence with the mainstem Feather River upstream to Daguerre Dam (39°12′35″ N./ 121°26′33″ W.).

(3) *Coastal bays and estuaries:* Critical habitat is designated to include the following coastal bays and estuaries in California, Oregon, and Washington:

(i) Central Valley, California. All tidally influenced areas of San Francisco Bay, San Pablo Bay, Suisun Bay, and the Sacramento-San Joaquin Delta up to the elevation of mean higher high water, including tributaries upstream to the head of tide. Designated areas in the Sacramento-San Joaquin Delta include all waterways within the area defined in California Water Code Section 12220, except for the following excluded slough areas: Fivemile Slough (all reaches upstream from its confluence with Fourteenmile Slough at 38°00′50″ N./ 121°22′09″ W.); Sevenmile Slough (all reaches between Threemile Slough at 38°06′55″ N./ 121°40′55″ W. and Jackson Slough at 38°06′59″ N./ 121°37′44″ W.); Snodgrass Slough (all reaches upstream from Lambert Road at 38°19′14″ N./ 121°31′08″ W.); Tom Paine Slough (all reaches upstream from its confluence with Middle River at 37°47′25″ N./ 121°25′08″ W.); and Trapper Slough (all reaches upstream from 37°53′36″ N./ 121°29′15″ W.).

(ii) Humboldt Bay, California: All tidally influenced areas of Humboldt Bay up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(iii) Coos Bay, Oregon. All tidally influenced areas of Coos Bay up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(iv) Winchester Bay, Oregon. All tidally influenced areas of Winchester Bay up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(v) Yaquina Bay, Oregon. All tidally influenced areas of Yaquina Bay up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(vi) Lower Columbia River, Washington and Oregon. All tidally influenced areas of the Columbia and Willamette Rivers downstream of Bonneville Dam and Willamette Falls and up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(vii) Willapa Bay, Washington. All tidally influenced areas of Willapa Bay up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(viii) Grays Harbor, Washington. All tidally influenced areas of Grays Harbor up to the elevation of mean higher high water, including tributaries upstream to the head of tide.

(b) *Primary constituent elements.* The primary constituent elements essential for the conservation of the Southern DPS of green sturgeon are:

(1) *For freshwater riverine systems:*

(i) Food resources. Abundant prey items for larval, juvenile, subadult, and adult life stages.

(ii) Substrate type or size (*i.e.*, structural features of substrates). Substrates suitable for egg deposition and development (*e.g.*, bedrock sills and shelves, cobble and gravel, or hard clean sand, with interstices or irregular surfaces to ''collect'' eggs and provide protection from predators, and free of excessive silt and debris that could smother eggs during incubation), larval development (*e.g.*, substrates with interstices or voids providing refuge from predators and from high flow conditions), and subadults and adults (*e.g.*, substrates for holding and spawning).

(iii) Water flow. A flow regime (*i.e.*, the magnitude, frequency, duration, seasonality, and rate-of-change of fresh water discharge over time) necessary for normal behavior, growth, and survival of all life stages.

(iv) Water quality. Water quality, including temperature, salinity, oxygen content, and other chemical characteristics, necessary for normal behavior, growth, and viability of all life stages.

(v) Migratory corridor. A migratory pathway necessary for the safe and timely passage of Southern DPS fish within riverine habitats and between riverine and estuarine habitats (*e.g.*, an unobstructed river or dammed river that still allows for safe and timely passage).

(vi) Depth. Deep (≥5 m) holding pools for both upstream and downstream holding of adult or subadult fish, with adequate water quality and flow to maintain the physiological needs of the holding adult or subadult fish.

(vii) Sediment quality. Sediment quality (*i.e.*, chemical characteristics) necessary for normal behavior, growth, and viability of all life stages.

(2) *For estuarine habitats:*

(i) Food resources. Abundant prey items within estuarine habitats and substrates for juvenile, subadult, and adult life stages.

(ii) Water flow. Within bays and estuaries adjacent to the Sacramento River (*i.e.*, the Sacramento-San Joaquin Delta and the Suisun, San Pablo, and San Francisco bays), sufficient flow into the bay and estuary to allow adults to successfully orient to the incoming flow and migrate upstream to spawning grounds.

(iii) Water quality. Water quality, including temperature, salinity, oxygen content, and other chemical characteristics, necessary for normal behavior, growth, and viability of all life stages.

(iv) Migratory corridor. A migratory pathway necessary for the safe and timely passage of Southern DPS fish within estuarine habitats and between estuarine and riverine or marine habitats.

(v) Depth. A diversity of depths necessary for shelter, foraging, and migration of juvenile, subadult, and adult life stages.

(vi) Sediment quality. Sediment quality (*i.e.*, chemical characteristics) necessary for normal behavior, growth, and viability of all life stages.

(3) *For nearshore coastal marine areas:*

(i) Migratory corridor. A migratory pathway necessary for the safe and timely passage of Southern DPS fish within marine and between estuarine and marine habitats.

(ii) Water quality. Nearshore marine waters with adequate dissolved oxygen levels and acceptably low levels of contaminants (*e.g.*, pesticides, organochlorines, elevated levels of heavy metals) that may disrupt the normal behavior, growth, and viability of subadult and adult green sturgeon.

(iii) Food resources. Abundant prey items for subadults and adults, which may include benthic invertebrates and fishes.

(c) Maps of proposed critical habitat for the Southern DPS of green sturgeon follow:

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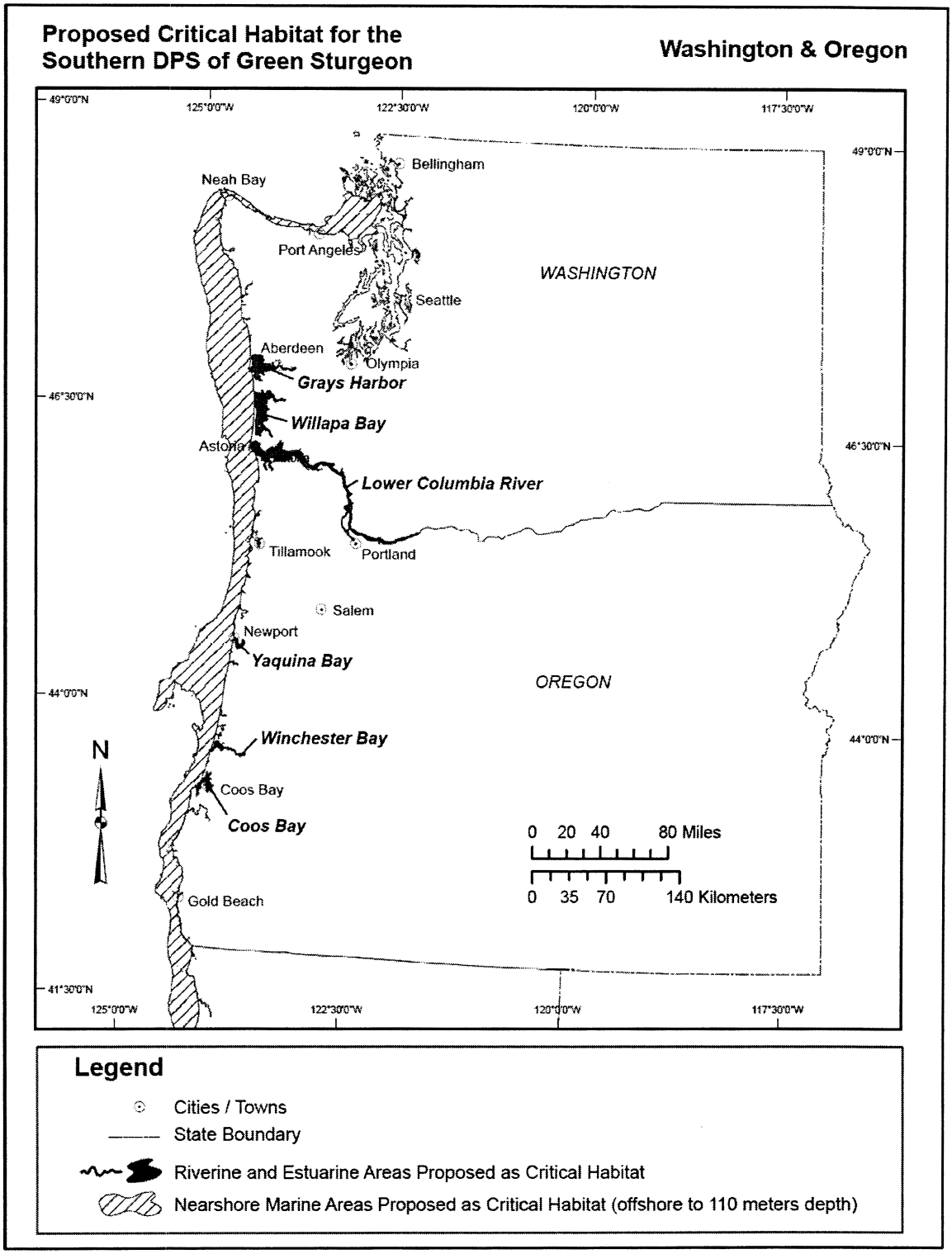
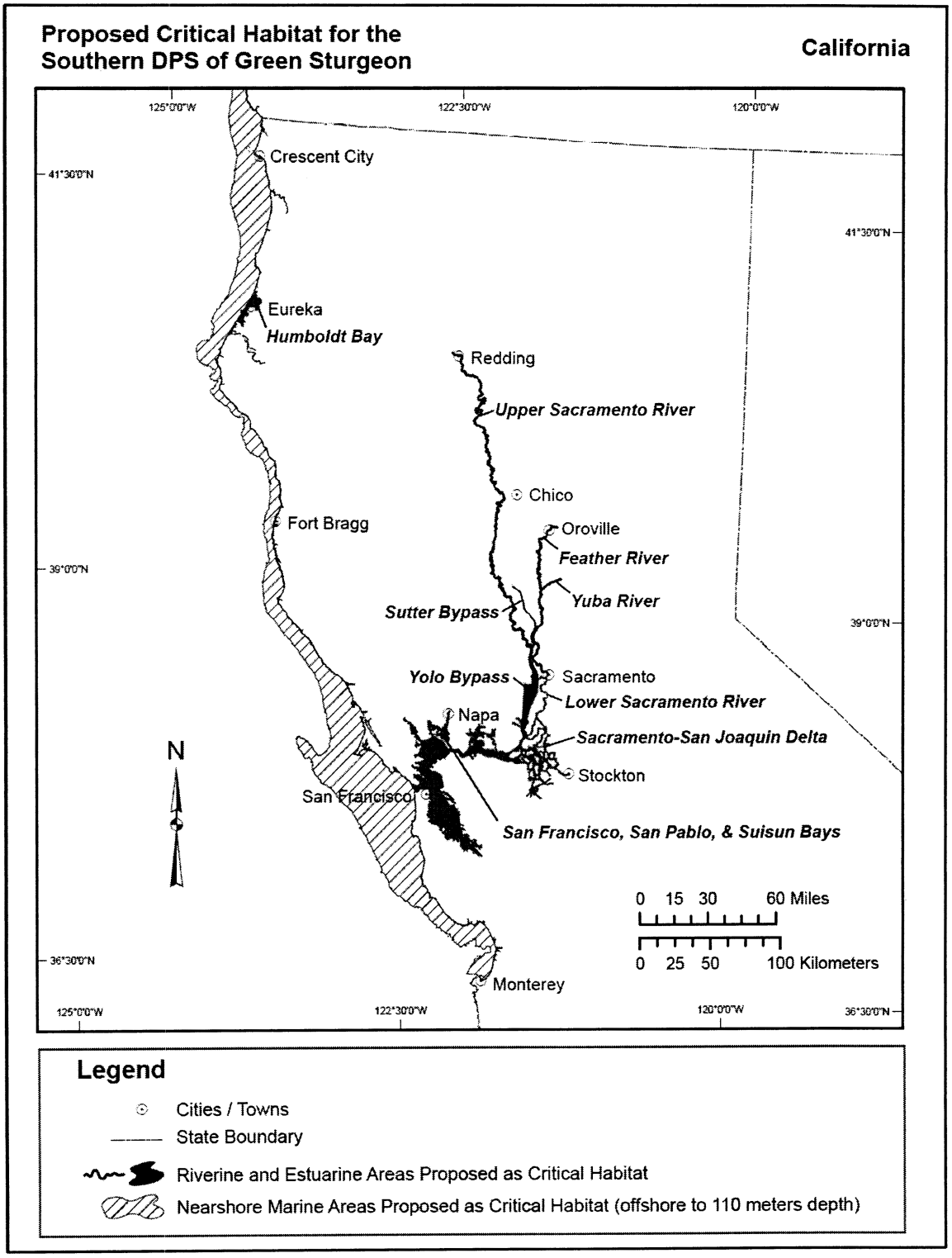

Proposed Critical Habitat for the Southern DPS of Green Sturgeon
Washington & Oregon
49°0'0"N
125°0'0"W
122°30'0"W
120°0'0"W
117°30'0"W
46°30'0"N
44°0'0"N
41°30'0"N
Bellingham
Neah Bay
Port Angeles
WASHINGTON
Seattle
Aberdeen
Olympia
Grays Harbor
Willapa Bay
Astoria
Lower Columbia River
Tillamook
Portland
Salem
Newport
Yaquina Bay
OREGON
Winchester Bay
Coos Bay
Coos Bay
Gold Beach
N
0 20 40 80 Miles
0 35 70 140 Kilometers
Legend
Cities / Towns
State Boundary
Riverine and Estuarine Areas Proposed as Critical Habitat
Nearshore Marine Areas Proposed as Critical Habitat (offshore to 110 meters depth)



[FR Doc. E8–20632 Filed 9–5–08; 8:45 am]
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Federal Register

Monday,
September 8, 2008

Part III

Department of Housing and Urban Development

24 CFR Part 26

Revision of Hearing Procedures; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 26

[Docket No. FR–5084–P–01]

RIN 2501–AD24

Revision of Hearing Procedures

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the hearing procedures before hearing officers who have the responsibility for adjudicating those matters that do not raise issues under the Administrative Procedure Act (APA). This proposed rule would also amend the hearing procedures before Administrative Law Judges (ALJs) who have the responsibility for adjudicating those matters that are subject to the requirements of the APA. Specifically, the proposed rule would modify pleading and motion requirements of the hearing procedures. It would also amend the discovery and deposition requirements to clarify the hearing officers' discovery procedures and to specifically allow for written interrogatories, in addition to depositions, requests for production of documents, and requests for admissions. A new provision allowing for written interrogatories would be added to the hearing procedures, and the proposed rule would also modify the procedures for the review of hearing officers' determinations. Additionally, the proposed rule would amend the discovery, appeal, and judicial review procedures related to hearings that are conducted pursuant to the APA. The proposed changes to the regulations would better reflect current practice and would conform the regulations more closely to statutory requirements.

DATES: *Comment Due Date:* November 7, 2008.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0001.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dane Narode, Acting Associate General Counsel, Office of Program Enforcement, Administrative Proceedings Division, Department of Housing and Urban Development, 1250 Maryland Avenue, Suite 200, Washington, DC 20024–0500; telephone 202–708–2350 (this is not a toll-free number); e-mail address: *Dane.M.Narode@hud.gov.* Hearing- or speech-impaired individuals may access the voice telephone number listed above by calling the toll-free Federal Information Relay Service during working hours at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

HUD's regulations implementing rules of procedure for hearings are located at 24 CFR part 26. Subpart A of part 26 applies to those hearing procedures before hearing officers who have the responsibility for adjudicating those matters that do not raise issues under the APA. HUD utilizes these rules of procedure with respect to determinations by the Multifamily Participation Review Committee, to: (1) Hearings conducted pursuant to referrals by debarring or suspending officials under 2 CFR part 2424; (2) hearings conducted pursuant to 24 CFR 17.150–17.170; and (3) other administrative disputes. Subpart B of part 26 applies to those hearing procedures before ALJs who have the responsibility for adjudicating those matters that are subject to the requirements of the APA.

II. This Proposed Rule

This proposed rule would amend HUD's hearing procedures to reflect current practice and to more closely conform to applicable statutes; the hearing provisions of the APA; and parts 25, 28, and 30 of this title. Additionally, the sections would be reordered to better track the normal course of a hearing conducted under this part. The sections would be revised as follows:

Current part 26	Proposed part 26
26.1	26.1
26.2	26.2
26.3	26.4
26.4	26.3
26.5	26.5
26.6	26.6
26.7	26.7
26.8	26.8
26.9	26.12
26.10	26.13
26.11	26.14
26.12	26.15
26.13	26.16
26.14	26.9
26.15	26.10
26.16	26.11
26.17	26.18
26.18	26.20
26.19	26.19
26.20	26.22
26.21	26.17
26.22	26.23
26.23	26.24
26.24	26.25
26.25	26.26
26.26	26.27
26.27	26.28
26.28	26.29
26.29	26.32
26.30	26.33
26.31	26.35
26.32	26.36
26.33	26.37

Current part 26	Proposed part 26
26.34	26.31
26.35	26.30
26.36	26.34
26.37	26.38
26.38	26.40
26.39	26.41
26.40	26.39
26.41	26.42
26.42	26.43
26.43	26.44
26.44	26.45
26.45	26.46
26.46	26.47
26.47	26.49
26.48	26.48
26.49	26.50
26.50	26.52
26.51	26.53
26.52	26.54
26.53	26.55
26.54	26.56

This section of the preamble discusses the proposed regulatory changes.

A. Amendments to Subpart A—Hearings Before Hearing Officers

Subpart A of part 26 contains the procedures for hearings before hearing officers. This proposed rule would amend subpart A to make the following revisions:

In § 26.1, the proposed rule would remove references to hearings conducted in matters arising under 24 CFR part 25, since those hearings would now be conducted in accordance with the provisions of subpart B of this part. A new paragraph (10) would be added to § 26.2 to clarify that the hearing officer shall have the authority necessary to carry out the duties of the hearing officer conducting hearings under this subpart.

The title of the newly designated § 26.4 would be changed to ''Sanctions'' to more clearly indicate the section contents and would be revised to include more specific guidance on the imposition of sanctions. For clarity and ease of use, § 26.5 would be divided into several paragraphs. Section 26.6 would be clarified to state that the attorneys within the Office of General Counsel will serve as the Department's representatives.

Newly designated § 26.9 would be divided into several paragraphs and minor changes would be made to clarify the form and filing requirements. Additionally, redesignated § 26.10 would be revised to update the methods and clarify the provisions concerning service. Newly designated § 26.11 would be revised to more closely track the similar provisions in subpart B.

The newly designated § 26.13 would be amended to provide the hearing officer with additional flexibility to designate a time period within which a complaint must be served and would be revised to clarify that the complaint must set forth both the factual and legal grounds for the action.

Newly designated § 26.14 would be broken into sections for clarity. Redesignated § 26.15 would clarify that Respondents may amend without leave under the provisions of amendment by right in paragraph (a).

The newly designated § 26.16 would be amended to state that, whenever possible, requests for action by the hearing officer should be made by motion. This revised section would also revise the name of the response to the motion for clarity and would extend the time period for response to 10 days. Additionally, this revised section would more clearly provide for motions to extend deadlines, would allow for the submission of proposed orders with written motions, would clarify the provisions concerning extensions of time, and would specifically provide for motions for summary judgment.

The discovery provisions in redesignated §§ 26.18–26.22 would be revised to more closely track the provisions of the Federal Rules of Civil Procedure, which have always been used as guidance in the conduct of hearings under this part. Specifically, the redesignated § 26.18 would revise and expand the discovery provisions to allow the use of written interrogatories, in addition to depositions, requests for production of documents, and requests for admissions. The newly designated §§ 26.19 and 26.20 would be revised to incorporate more definite requirements for requesting the production of documents and for depositions and objections to depositions. A new § 26.21 would be added to allow for a limited number of interrogatories in discovery. The redesignated § 26.22 would be revised to clarify the procedure for objections to admissions of facts and documents, and the title of that section would be changed to ''Requests for admissions'' to more clearly indicate the section contents.

The newly designated § 26.24 would be revised to encourage the parties to enter into stipulations whenever possible. Redesignated § 26.25 would clarify: (1) That the hearing officer's determination and order is final unless a party timely appeals it in accordance with redesignated § 26.26, and (2) would require the determination to provide information on such review, if any. The redesignated § 26.26 would modify the provisions regarding Secretarial review of the determinations of hearing officers by specifically providing that the Debarring Official shall have authority to review determinations in suspension and debarment proceedings, not the Secretary, by incorporating more detailed requirements for the briefs both in support of and in opposition to the appeal and by providing for the Secretary's discretion to extend deadlines. Furthermore, redesignated § 26.26 would include additional provisions about evidence in the record and ex parte communications, and combine and expand upon provisions concerning the final, written determination.

Redesignated § 26.27 would be broken down into sections, for clarity.

B. Amendments to Subpart B—Hearings Pursuant to the Administrative Procedure Act

Subpart B of part 26 contains the procedures for hearings conducted on the record pursuant to the APA. This proposed rule would amend subpart B to make the following revisions:

The redesignated § 26.29 will include a definition of ''Respondent'' in the regulations and would modify the title of the docket clerk.

A new subheading titled ''Administrative Law Judge'' would be inserted before the newly designated § 26.32. The newly designated § 26.32 would be revised to redesignate paragraph (n) as (o) and to include a new paragraph (n) clarifying the ALJ's authority to extend deadlines. Minor clarifications to the specific language of the section would be made to the new §§ 26.34 and 26.35.

A new subheading titled ''Parties'' would be inserted before the redesignated § 26.36.

Redesignated § 26.38 would require the complaint to be filed with the Office of Administrative Law Judges upon issuance and would require the Respondent's response to be filed with the same office, with a copy served upon the Department in accordance with the procedures set forth in the complaint.

Redesignated § 26.40 would be revised to specifically provide for motions for summary judgment, would be revised to extend the time period for response to a motion to 10 days, and would more clearly provide for motions for time extensions. The newly designated § 26.42 would be amended to include more specific provisions for conduct of discovery under this subpart. As a result, the discovery procedures of subpart B will substantially conform to those of subpart A, and parties will be able to understand all applicable discovery procedures without having to reference the Federal Rules of Civil

Procedure. Additionally, § 26.42 would provide that in discovery in Program Fraud Civil Remedies Act (PFCRA) actions, the defendant may review documents that relate to the allegations set out in the complaint.

The redesignated § 26.44 would be divided into additional paragraphs for clarity. The newly designated § 26.45 would be amended to clarify the commencement dates and location of the hearing in PFCRA matters. Redesignated § 26.47 would be revised to provide additional guidance and clarity.

Section 26.49 would be amended to require that the hearing be recorded by a HUD-designated reporter and that the parties may obtain copies of the transcript.

Section 26.50(a) would clarify that the initial decision of the ALJ does not become effective unless it becomes final agency action on its own under § 26.50(c) or 26.52(l) or if it is incorporated into the final agency action by the Secretary's decision under § 26.52(l). Redesignated § 26.52 would be amended to provide that all parties may request Secretarial review of determinations in PFCRA matters. Redesignated § 26.52 would also be amended to incorporate more detailed requirements for the briefs both in support of and in opposition to the appeal, to provide for the discretion to extend deadlines, and to combine and expand upon provisions concerning the final written decision.

A new § 26.51 would establish procedures for seeking interlocutory Secretarial review of the rulings of an ALJ by motion for certification or by petition to the Secretary.

Redesignated § 26.54 would be revised to eliminate the prohibition that the Government cannot seek judicial review of an adverse determination in PFCRA matters. The revision would bring the Government's right to review into conformity with that in non-PFCRA matters.

III. Small Business Concerns Related to Board Enforcement Actions

With respect to enforcement actions undertaken pursuant to the procedures provided in this proposed rule, HUD is cognizant that section 222 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) requires the Small Business and Agriculture Regulatory Enforcement Ombudsman to ''work with each agency with regulatory authority over small businesses to ensure that small business concerns that receive or are subject to an audit, on-site inspection, compliance assistance effort, or other enforcement related communication or contact by agency personnel are provided with a means to comment on the enforcement activity conducted by this personnel.'' To implement this statutory provision, the Small Business Administration has requested that federal agencies include the following language on agency publications and notices that are provided to small business concerns at the time the enforcement action is undertaken. The language is as follows:

Your Comments Are Important

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of [insert agency name], you will find the necessary comment forms at *www.sba.gov/ombudsman* or call 1–888–REG–FAIR (1–888–734–3247).

In accordance with its notice describing HUD's actions on the implementation of SBREFA, which was published on May 21, 1998 (63 FR 28214), HUD will include the language cited above on notices implementing enforcement actions, to ensure that small entities have the full means to comment on the enforcement activity conducted by HUD.

IV. Findings and Certifications

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This proposed rule would clarify pleading, discovery, and motion requirements that apply to hearings before HUD hearing officers and ALJs, respectively, by codifying current practice and by eliminating the need for parties to refer to outside sources, such as the Federal Rules of Civil Procedure, for routine requirements. Procedures that apply to parties in matters adjudicated in such hearings will not change significantly as a result of this rule, whether or not parties are small entities. These revisions impose no significant economic impact on a substantial number of small entities. Therefore, the undersigned certifies that this rule will not have a significant impact on a substantial number of small entities.

Notwithstanding HUD's determination that this rule will not have a significant economic impact on a substantial number of small entities, HUD specifically invites comments regarding less burdensome alternatives to this rule that will meet HUD's program responsibilities.

Environmental Impact

This proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*)

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of Section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531–1538) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This proposed rule would not impose any federal mandates on any state, local, or tribal government or the private sector within the meaning of UMRA.

List of Subjects for 24 CFR Part 26

Administrative practice and procedure.

Accordingly, for the reasons discussed in the preamble, HUD proposes to revise 24 CFR part 26 to read as follows:

PART 26—HEARING PROCEDURES

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Authority: 42 U.S.C. 3535(d).

Subpart A—Hearings Before Hearing Officers

§ 26.1 Purpose and scope.

This part sets forth rules of procedure in certain proceedings of the Department of Housing and Urban Development presided over by a hearing officer. These rules of procedure apply to administrative sanction hearings pursuant to 2 CFR part 2424 and to hearings with respect to determinations by the Multifamily Participation Review Committee pursuant to 24 CFR part 200, subpart H, to the extent that these regulations are not inconsistent and unless these regulations provide otherwise. They also apply in any other case where a hearing is required by statute or regulation, to the extent that rules adopted under such statute or regulation are not inconsistent.

Hearing Officer

§ 26.2 Hearing officer, powers, and duties.

(a) *Hearing officer.* Proceedings conducted under these rules shall be presided over by a hearing officer who shall be an Administrative Law Judge or Office of Appeals Administrative Judge authorized by the Secretary or designee to conduct proceedings under this part.

(b) *Time and place of hearing.* The hearing officer shall set the time and place of any hearing and shall give reasonable notice to the parties.

(c) *Powers of hearing officers.* The hearing officer shall conduct a fair and impartial hearing and take all action necessary to avoid delay in the disposition of proceedings and to maintain order. The hearing officer shall have all powers necessary to those ends, including, but not limited to, the power:

(1) To administer oaths and affirmations;

(2) To cause subpoenas to be issued as authorized by law;

(3) To rule upon offers of proof and receive evidence;

(4) To order or limit discovery as the interests of justice may require;

(5) To regulate the course of the hearing and the conduct of the parties and their counsel;

(6) To hold conferences for the settlement or simplification of the issues by consent of the parties;

(7) To consider and rule upon all procedural and other motions appropriate in adjudicative proceedings;

(8) To take notice of any material fact not appearing in evidence in the record that is properly a matter of judicial notice;

(9) To make and file determinations; and

(10) To exercise such other authority as is necessary to carry out the responsibilities of the hearing officer under subpart A of this part.

§ 26.3 Ex parte communications.

(a) *Definition.* An ex parte communication is any communication with a hearing officer, direct or indirect, oral or written, concerning the merits or procedures of any pending proceeding that is made by a party in the absence of any other party.

(b) *Prohibition of ex parte communications.* Ex parte communications are prohibited except where:

(1) The purpose and content of the communication have been disclosed in advance or simultaneously to all parties; or

(2) The communication is a request for information concerning the status of the case.

(c) *Procedure after receipt of ex parte communication.* Any hearing officer who receives an ex parte communication that the hearing officer knows or has reason to believe is unauthorized shall promptly place the communication, or its substance, in all files and shall furnish copies to all parties. Unauthorized ex parte communications shall not be taken into consideration in deciding any matter in issue.

§ 26.4 Sanctions.

(a) The hearing officer may sanction a person, including any party or representative, for failing to comply with an order, rule, or procedure governing the proceeding; failing to prosecute or defend an action; or engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) If a party refuses or fails to comply with an order of the hearing officer,

including an order compelling discovery, the hearing officer may enter any appropriate order necessary to the disposition of the hearing including a determination against the noncomplying party, including but not limited to, the following:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, regard each matter about which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with the order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; or

(4) Strike any part of the pleadings or other submissions of the party failing to comply with the order.

(d) If a party fails to prosecute or defend an action brought under subpart A of this part, the hearing officer may dismiss the action or may issue an initial decision against the non-prosecuting or defending party.

(e) The hearing officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion.

§ 26.5 Disqualification of hearing officer.

(a) When a hearing officer believes there is a basis for disqualification in a particular proceeding, the hearing officer shall withdraw by notice on the record and shall notify the Secretary and the official initiating the action under appeal.

(b) Whenever any party believes that the hearing officer should be disqualified from presiding in a particular proceeding, the party may file a motion with the hearing officer requesting the hearing officer to withdraw from presiding over the proceedings. This motion shall be supported by affidavits setting forth the alleged grounds for disqualification.

(c) Upon the filing of a motion and affidavit, the hearing officer shall proceed no further in the case until the matter of disqualification is resolved.

(d) If the hearing officer does not withdraw, a written statement of his or her reasons shall be incorporated in the record and the hearing shall proceed, unless the decision is appealed in accordance with the procedures set forth in § 26.27.

Representation of the Parties

§ 26.6 Department representative.

In each case heard before a hearing officer under this part, the Department shall be represented by attorneys from the Office of General Counsel.

§ 26.7 Respondent's representative.

The party against whom the administrative action is taken may be represented at hearing, as follows:

(a) Individuals may appear on their own behalf;

(b) A member of a partnership or joint venture may appear on behalf of the partnership or joint venture;

(c) A bona fide officer may appear on behalf of a corporation or association upon a showing of adequate authorization;

(d) An attorney who files a notice of appearance with the hearing officer may represent any party. For purposes of this paragraph, an attorney is defined as a member of the bar of a federal court or of the highest court of any state or territory of the United States; or

(e) An individual not included within paragraphs (a) through (d) of this section may represent the respondent upon an adequate showing, as determined by the hearing officer, that the individual possesses the legal, technical, or other qualifications necessary to advise and assist in the presentation of the case.

§ 26.8 Standards of practice.

Attorneys shall conform to the standards of professional and ethical conduct required of practitioners in the courts of the United States and by the bars of which the attorneys are members. Any attorney may be prohibited by the hearing officer from representing a party if the attorney is not qualified under § 26.7 or if such action is necessary to maintain order in or the integrity of the pending proceeding.

Pleadings and Motions

§ 26.9 Form and filing requirements.

(a) *Filing.* Unless otherwise provided by statute, rule, or regulation:

(1) Requests for hearings shall be filed with the Office of General Counsel's Docket Clerk, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. The OGC Docket Clerk shall assign the docket number and forward the case to HUD's Office of Appeals.

(2) All other pleadings, submissions, and documents should be filed directly with the appropriate hearing officer.

(3) Filing may be made by first class mail, delivery, facsimile transmission, or electronic means; however, the hearing officer may place reasonable limits on filing by facsimile or electronic means. Duplicate copies are not required unless so ordered by the hearing officer. A document is considered timely filed if postmarked on or before the date due or delivered to the appropriate person by the date due.

(b) *Title.* Documents shall show clearly the title of the action and the docket number assigned by the Docket Clerk.

(c) *Form.* To the fullest extent possible, all documents shall be printed or typewritten in clear, legible form.

§ 26.10 Service.

(a) *Method of Service.* One copy of all pleadings, motions, and other documents required or permitted under these rules shall be served upon all parties by the person filing them and shall be accompanied by a certificate of service stating how and when such service has been made. Whenever these rules require or permit service to be made upon a party represented by an attorney, the service shall be made upon the attorney, unless service upon the party is ordered by the hearing officer. Service shall be made by delivery, by first class mail or overnight delivery to that person's last known address, by facsimile transmission, or by electronic means; however, the hearing officer may place reasonable limits on service by facsimile transmission or electronic means. Delivery of a copy within this rule means: Handing it to the person to be served; or leaving it at that person's office with a clerk or other person in charge; or, if there is no one in charge, leaving it in a conspicuous place in the office; or, if the office is closed or the person to be served has no office, leaving it at that person's residence or usual place of abode with some person of suitable age and discretion who resides there. Service by mail, overnight delivery, facsimile transmission, or electronic means is complete upon deposit in a mail box, or upon posting, or upon electronic transmission.

(b) *Proof of Service.* Proof of service shall not be required unless the fact of service is put in issue by appropriate motion or objection on the part of the person allegedly served. In these cases, service may be established by written receipt signed by or on behalf of the person to be served, or may be established prima facie by affidavit, certificate of service of mailing, or electronic receipt of sending.

§ 26.11 Time computation.

(a) *Generally.* Computation of any period of time prescribed or allowed by this part shall begin with the first business day following the day on which the act, event, development, or default initiating the period of time occurred. When the last day of the period computed is a Saturday, Sunday, national holiday, or other day on which

the Department of Housing and Urban Development is closed, the period shall run until the end of the next following business day. When any prescribed or allowed period of time is 7 days or less, each of the Saturdays, Sundays, and national holidays shall be excluded from the computation of the prescribed or allowed period.

(b) *Entry of orders.* In computing any time period involving the date of the issuance of an order or decision by a hearing officer, the date of the issuance is the date the order or decision is served on the parties by the hearing officer or Docket Clerk.

(c) *Service by mail.* If a document is served by mail, 3 days shall be added to the time permitted for a response.

(d) *Extensions of time periods.* Except where mandated by statute, the hearing officer (or in the case of a review under §§ 26.26 and 26.27, the Secretary or designee) may upon motion enlarge the time within which any act required by these rules must be performed where necessary to avoid prejudicing the public interest or the rights of the parties.

§ 26.12 Notice of administrative action.

In every case, there shall be a notice of administrative action. The notice shall be in writing and inform the party of the nature of that administrative action. The notice shall state the reasons for the proposed or imposed action, except where general terms are permitted by 2 CFR part 2424, and shall inform the party of any right to a hearing to challenge the administrative action, and the manner and time in which to request such hearing. A supplemental notice may be issued in the discretion of the initiating official to add to or modify the reasons for the action.

§ 26.13 Complaint.

(a) *Respondent.* A complaint shall be served upon the party against whom an administrative action is taken, who shall be called the respondent.

(b) *Grounds.* The complaint shall state the legal and factual grounds upon which the administrative action is based. The grounds set forth in the complaint may not contain allegations beyond the scope of the notice of administrative action or any amendment thereto.

(c) *Notice of administrative action as complaint.* A notice of administrative action may serve as a complaint provided the notice states it is also a complaint and complies with paragraph (b) of this section.

(d) *Timing.* When the notice does not serve as a complaint, the complaint shall be served on or before the 30th day after the referral to a hearing officer or a request for hearing is made, or within any other time period designated by the hearing officer.

§ 26.14 Answer.

(a) Respondent shall file an answer within 30 days of receipt of the complaint, unless otherwise specified in this title or ordered by the hearing officer.

(b) The answer shall:

(1) Respond specifically to each factual allegation contained in the complaint;

(2) Specifically plead any affirmative defense; and

(3) Set forth any mitigating factors or extenuating circumstances.

(c) A general denial shall not be permitted. Allegations are admitted when not specifically denied in respondent's answer.

§ 26.15 Amendments and supplemental pleadings.

(a) *Amendments.* (1) By right: The Department may amend its complaint without leave at any time within 30 days of the date the complaint is filed or at any time before respondent's responsive pleading is filed, whichever is later. Respondent may amend its answer without leave at any time within 30 days of filing of its answer. A party shall plead in response to an amended pleading within 15 days of receipt of the amended pleading.

(2) By leave: Upon conditions as are necessary to avoid prejudicing the public interest and the rights of the parties, the hearing officer may allow amendments to pleadings upon motion of any party.

(3) Conformance to evidence: When issues not raised by the pleadings, but reasonably within the scope of the proceeding initiated by the complaint, are tried by express or implied consent to the parties, they shall be treated in all respects as if they had been raised in the pleadings, and amendments of the pleadings necessary to make them conform to the evidence shall be allowed at any time.

(b) *Supplemental pleadings.* The hearing officer may, upon reasonable notice, permit service of a supplemental pleading concerning transactions, occurrences, or events that have happened or been discovered since the date of prior pleadings.

§ 26.16 Motions.

(a) *Motions.* Requests for rulings or actions to be taken by the hearing officer should be made, wherever appropriate, in the form of a motion. All motions from the commencement of the action until the issuance of a decision shall be addressed to the hearing officer, and shall be served upon all parties to the proceeding.

(b) *Content.* All written motions shall state the particular order, ruling, or action desired and the grounds for granting the motion. The parties may submit a proposed order with any motion.

(c) *Responses to motions.* Within 10 days after receipt of any written motion, or within any other period as may be designated by the hearing officer, the opposing party shall respond to the motion and set forth any objections to the motion. Failure to file a timely response to the motion may constitute a party's consent to the granting of the motion. The moving party shall have no right to reply, except as permitted by the hearing officer.

(d) *Motions for extensions of time.* Either party may file a motion for extension. At the discretion of the hearing officer, a motion for an extension of time may be granted for good cause at any time, notwithstanding an objection or any reply to the motion consistent with the provisions of § 26.2(c)(5) and (7). The hearing officer may waive the requirements of this section as to motions for extensions of time.

(e) *Oral argument.* The hearing officer may order oral argument on any motion.

(f) *Motions for summary judgment.*

(1) A party claiming relief or a party against whom relief is sought may timely move, with or without supporting affidavits, for summary judgment on all or part of the claim.

(2) Objections in the consideration of summary judgment motions or answers thereto based upon a failure to strictly comply with the provisions of Rule 56 of the Federal Rules of Civil Procedure may, at the discretion of the hearing officer, be overruled.

(g) *Motions for dismissal.* When a motion to dismiss the proceeding is granted, the hearing officer shall issue a determination and order in accordance with the provisions of § 26.25.

Discovery

§ 26.17 Prehearing conference.

(a) *Prehearing conference.* The hearing officer may, *sua sponte* or at the request of any party, direct counsel for all parties to confer with the hearing officer before the hearing for the purpose of considering:

(1) Simplification and clarification of the issues;

(2) Stipulations and admissions of fact and of the contents and authenticity of documents;

(3) The disclosure of the names of witnesses;

(4) Matters of which official notice will be taken;

(5) Other matters as may aid in the orderly disposition of the proceeding, including disclosure of the documents or other physical exhibits that will be introduced into evidence in the course of the proceeding.

(b) *Recordation of prehearing conference.* The prehearing conference shall, at the request of any party, be recorded or transcribed.

(c) *Order on prehearing conference.* The hearing officer shall enter in the record an order that states the rulings upon matters considered during the conference, together with appropriate directions to the parties. The order shall control the subsequent course of the proceeding, subject to modifications upon good cause shown.

§ 26.18 Discovery.

(a) *General.* The parties are encouraged to engage in voluntary discovery procedures, which may commence at any time after an answer has been filed. Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. For good cause, the hearing officer may order discovery of any matter relevant to the subject matter involved in the action. To be relevant, information need not be admissible at the hearing, if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. Each party shall bear its own expenses associated with discovery. Discovery may include:

(1) Requests for production of documents as set forth in § 26.19;

(2) Depositions as set forth in § 26.20;

(3) Written interrogatories as set forth in § 26.21; and

(4) Requests for admissions as set forth in § 26.22.

(b) *Supplementation of responses.* A party who has responded to a request for discovery with a response is under a duty to timely amend a prior response to an interrogatory, request for production, or request for admission if so ordered by the hearing officer, or if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.

(c) *Requesting an order.* In connection with any discovery procedure, by motion addressed to the hearing officer and upon a showing of a good faith attempt to resolve the issue without the hearing officer's intervention, either party may:

(1) Request an order compelling a response with respect to any objection to or other failure to respond to the discovery requested or any part thereof, or any failure to respond as specifically requested, or

(2) Request a protective order limiting the scope, methods, time and place for discovery, and provisions for protecting privileged information or documents.

(d) *Limitations.* (1) By order, the hearing officer may set or alter limits on the number of document requests, depositions, and interrogatories, or the length of depositions.

(2) Orders compelling discovery shall be issued only where such discovery will not compel the disclosure of privileged information, unduly delay the hearing, or result in prejudice to the public interest or the rights of the parties, and upon a showing of good cause.

(3) Protective orders may be issued by a hearing officer if the hearing officer determines such an order is necessary to protect a party or other person from annoyance, embarrassment, oppression, or undue burden or expense because:

(i) The discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;

(ii) The party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or

(iii) The burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

(4) A party need not provide discovery of electronically stored information from sources that the party identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the party from whom discovery is sought must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the hearing officer may nonetheless order discovery from such sources if the requesting party shows good cause or, when the party's refusal to provide the information sought is solely due to undue expense, if the party seeking the discovery agrees to bear the expense associated with the request.

(e) *Refusal to honor discovery order.* When a party refuses to honor a discovery order, the hearing officer may issue such orders in regard to the refusal as justice shall require.

§ 26.19 Request for production of documents.

(a) *Request to produce.* Any party may serve upon any other party a written request to produce, and permit the party making the request, or someone acting on the requestor's behalf, to inspect, copy, test, or sample any designated documents—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained—translated, if necessary, by the respondent into reasonably usable form, or to inspect, copy, test, or sample any designated tangible things that constitute or contain matters within the scope of § 26.18(a) and which are in the possession, custody, or control of the party upon whom the request is served.

(b) *Procedure.* The request shall set forth, either by individual item or by category, the items to be inspected, and describe each with reasonable particularity. The request shall specify a reasonable time, place, and manner of making the inspection and performing the related acts. The request may specify the form or forms in which electronically stored information is to be produced.

(c) *Response to request to produce.* The party upon whom the request is served shall serve a written response within 20 days after service of the request. A shorter or longer time may be directed by the hearing officer, or in the absence of such an order, agreed to by the parties in a written document that shall be timely submitted to the hearing officer. The response shall state, with respect to each item or category, whether inspection and related activities will be permitted as requested. If there are any objections to any requests, including objections to the requested form or forms for producing electronically stored information, the response shall state the reasons for such objections. If objection is made to part of an item or category, the part shall be specified and inspection of the remaining parts shall be permitted. If objection is made to the requested format or forms for producing electronically stored information—or if no form was specified in the request—

the responding party must state the form or forms it intends to use. The party submitting the request may move for an order under § 26.18(c)(1) with respect to any objection to or other failure to respond to the request or any part thereof, or any failure to permit inspection as requested.

(d) *Form of production.* Unless the parties otherwise agree, or the hearing officer otherwise orders:

(1) A party who produces documents for inspection shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the request;

(2) If a request does not specify the format or forms for producing electronically stored information, a responding party must produce the information in a form or forms in which it is ordinarily maintained or in a form or forms that are reasonably usable; and

(3) A party need not produce the same electronically stored information in more than one form.

§ 26.20 Depositions.

(a) *Taking oral deposition.* A party may take the oral deposition of any person. Reasonable written notice of deposition shall be served upon the opposing party and the deponent. The attendance of a deponent may be compelled by subpoena where authorized by law or by other order of the hearing officer.

(b) *Testifying on oral deposition.* Each person testifying on oral deposition shall be placed under oath by the person before whom the deposition is taken. The deponent may be examined and cross-examined. The questions and the answers, together with all objections made, shall be recorded by the person before whom the deposition is to be taken, or under that person's direction.

(c) *Objections.* Objection may be made to questions or answers for any reason that would require the exclusion of the testimony under § 26.24 as if the witness were present and testifying at hearing. Objections shall be in short form, stating every ground for objection. Failure to object to any question or answer shall be considered a waiver of objection, unless the parties agree otherwise. Rulings on any objections shall be made by the hearing officer at hearing, or at such other time requested by motion. The examination shall proceed, with the testimony being taken subject to the objections; the deponent may be instructed not to answer only when necessary to preserve a privilege, to enforce a limitation directed by the hearing officer, or to present a motion for a protective order under § 26.18(c)(2).

(d) *Submission to deponent.* A transcript of the deposition shall be submitted to the deponent for examination and signature, unless submission is waived by the deponent and the parties. Any changes in form or substance that the deponent desires to make shall be entered upon the transcript by the person before whom the deposition was taken, with a statement of reasons given by the deponent for making them. The transcript shall then be signed by the deponent, unless the parties by stipulation waive the signing or the deponent is ill, cannot be found, or refuses to sign. If the transcript is not signed, the person before whom the deposition was taken shall sign it and state on the record the reason that it is not signed.

(e) *Certification and filing.* The person before whom the deposition was taken shall make a certification on the transcript as to its accuracy. Interested parties shall make their own arrangements with the person recording the testimony for copies of the testimony and the exhibits.

(f) *Deposition as evidence.* Subject to appropriate rulings by the hearing officer on objections, the deposition or any part may be introduced into evidence for any purpose if the deponent is unavailable. Only that part of a deposition that is received in evidence at a hearing shall constitute a part of the record in the proceeding upon which a decision may be based. Nothing in this rule is intended to limit the use of a deposition for impeachment purposes.

(g) *Payment of fees.* Fees shall be paid by the person upon whose application the deposition is taken.

§ 26.21 Written interrogatories.

(a) *Service of interrogatories.* Any party may serve upon any other party written interrogatories, not to exceed 25 in number, including all discrete subparts, unless additional interrogatories are agreed to by the parties or leave to serve additional interrogatories is granted by the hearing officer.

(b) *Response to interrogatories.* Within 20 days after service of the request, the party upon whom the interrogatories are served shall serve a written response, unless the parties agree in a written document submitted to the hearing officer or the hearing officer determines that a shorter or longer period is appropriate under the circumstances. The response shall specifically answer each interrogatory, separately and fully in writing, unless it is objected to, in which event the objecting party shall state the reasons for any objections with specificity. Any ground not stated in a timely objection is waived unless the party's failure to object is excused by the hearing officer for good cause shown. If objection is made to only part of an interrogatory, the objectionable part shall be specified and the party shall answer to the extent that the interrogatory is not objectionable.

(c) *Option to produce business records.* Where the answer to an interrogatory may be derived or ascertained from the business records, including electronically stored information, of the party upon whom the interrogatory has been served or from an examination, audit, or inspection of such business records, including a compilation, abstract, or summary thereof, and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained and to afford to the party serving the interrogatory reasonable opportunity to examine, audit, or inspect such records and to make copies, compilations, abstracts, or summaries. A specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can by the party served, the records from which the answer may be ascertained.

§ 26.22 Requests for admissions.

(a) Any party may serve upon any other party a written request for the admission of the genuineness of any relevant documents described in the request or of the truth of any relevant matters of fact. Copies of documents shall be delivered with the request unless copies have already been furnished. Each requested admission shall be considered admitted, unless within 30 days after service of the request, or within such other time as the parties may agree, or the hearing officer determines, the party from whom the admission is sought serves upon the party making the request either:

(1) A statement that:

(i) Denies specifically the relevant matters for which an admission is requested, or sets forth in detail the reasons why the party can neither truthfully admit nor deny them;

(ii) Fairly meets the substance of the requested admission and, when good faith requires that a party qualify an answer or deny only a part of the matter

of which an admission is requested, specifies as much of it as is true and qualifies or denies the remainder; and

(iii) Does not assert lack of information or knowledge as a reason for failure to admit or deny, unless the party states that the party has made reasonable inquiry, and that the information known or readily obtainable by the party is insufficient to enable the party to admit or deny; or

(2) Written objections to a requested admission that:

(i) State the grounds for the objection; and

(ii) Object to a requested admission, if necessary, either in whole or in part, on the basis of privilege or relevance.

(b) Responses to the request for admission on matters to which objections have been made may be deferred until the objection is ruled upon, but if written objections are made only to a part of a request, a response to the remainder of the request shall be provided.

(c) Any matter admitted under this rule is conclusively established unless the hearing officer, on motion, permits withdrawal or amendment of the admission. Admissions obtained pursuant to this procedure may be used in evidence only for the purposes of the pending action. The use of obtained admissions as evidence is permitted to the same extent and subject to the same objections as other evidence.

Hearings

§ 26.23 Public nature and timing of hearings; transcripts.

(a) *Public hearings.* All hearings in adjudicative proceedings shall be public.

(b) *Conduct of hearing.* Hearings shall proceed with all reasonable speed. The hearing officer may order recesses for good cause, stated on the record. The hearing officer may, for convenience of the parties or witnesses, or in the interests of justice, order that hearings be conducted outside of Washington, DC, and, if necessary, in more than one location.

(c) *Transcripts.* Hearings shall be recorded and transcribed only by a reporter designated by the Department under the supervision of the hearing officer. The original transcript shall be a part of the record and shall constitute the sole official transcript. Any party or a member of the public, at his own expense, may obtain copies of transcripts from the reporter.

§ 26.24 Rules of evidence.

(a) *Evidence.* Every party shall have the right to present its case or defense by oral and documentary evidence, unless otherwise limited by law or regulation, to conduct such cross-examination and to submit rebuttal evidence as may be required for a full and true disclosure of the facts. Irrelevant, immaterial, privileged, or unduly repetitious evidence shall be excluded. Unless otherwise provided for in this part, the Federal Rules of Evidence shall provide guidance to the hearing officer in the conduct of proceedings under this part, but shall not be binding. Parties may object to clearly irrelevant material, but technical and hearsay objections to testimony as used in a court of law will not be sustained.

(b) *Testimony under oath or affirmation.* All witnesses shall testify under oath or affirmation.

(c) *Objections.* Objections to the admission or exclusion of evidence shall be in short form, stating the grounds of objections. Rulings on objections shall be a part of the transcript. Failure to object to admission or exclusion of evidence or to any evidentiary ruling shall be considered a waiver of objection, but no exception to a ruling on an objection is necessary in order to preserve it for appeal.

(d) *Authenticity of documents.* Unless specifically challenged, it shall be presumed that all relevant documents are authentic. An objection to the authenticity of a document shall not be sustained merely on the basis that it is not the original.

(e) *Stipulations.* The parties may stipulate as to any relevant matters of fact. Stipulations may be received in evidence at a hearing, and when received shall be binding on the parties with respect to the matters stipulated. The parties are encouraged to enter into stipulations of fact whenever possible.

(f) *Official notice.* All matters officially noticed by the hearing officer shall appear on the record.

(g) *Burden of proof.* The burden of proof shall be upon the proponent of an action or affirmative defense, including, where applicable, mitigating factors, unless otherwise provided by law or regulation.

§ 26.25 Hearing officer's determination and order.

(a) *Scope of review.* The hearing officer shall conduct a de novo review of the administrative action to determine whether it is supported by a preponderance of the evidence, unless a different standard of proof is required by law or regulation. Each and every charge alleged by the Department need not be proven to support the administrative action. The hearing officer may modify or vacate the administrative action under review only upon a particularized finding of facts that justifies a deviation from the administrative action.

(b) *Closing of hearing.* At the discretion of the hearing officer, the closing of the record may be postponed in order to permit the admission of other evidence into the record. In the event further evidence is admitted, each party shall be given an opportunity to respond to such evidence.

(c) *Briefs.* Upon conclusion of the hearing, the hearing officer may request the parties to file proposed findings of fact and legal briefs. The hearing officer shall make a written determination and order based upon evidence and arguments presented by the parties. The determination shall be founded upon reliable and probative evidence. This determination and order shall be served upon all parties.

(d) *Bench decisions.* Where the parties agree and where appropriate in the judgment of the hearing officer, a bench decision will be issued.

(e) *Time period for issuance of decision.* The hearing officer shall endeavor to issue a determination within 60 days from the date of the closing of the record.

(f) *Finality of determination.* The determination and order shall be final unless a party timely appeals the determination in accordance with § 26.26. The determination shall inform the parties that, if provided for and consistent with Departmental regulations, any party may request, in writing, Secretarial review of the determination within 30 days after the hearing officer issues the determination, in accordance with § 26.26 of this part. The determination shall include the mailing address, facsimile number, and electronic submission information to which the request for Secretarial review should be sent. A request for Secretarial review may be made by mail, delivery, facsimile, or electronic submission.

Secretarial Review

§ 26.26 Review of determination of hearing officers.

(a) Except in matters arising under 2 CFR part 2424, any party may file with the Secretary an appeal within 30 days after the date that the hearing officer issues a determination or order. The Secretary or designee may extend the 30-day period, in the Secretary's sole discretion, for good cause.

(b) *Brief in support of appeal.* The appeal shall be accompanied by a written brief, not to exceed 15 pages, setting forth the party's specific objections to the determination or order

of the hearing officer and the party's supporting reasons for any objections. The appealing party may request leave to file a brief in excess of 15 pages for good cause shown. Alternative proposed findings and conclusions, if any, may be appended as an exhibit.

(c) *Briefs in opposition.* Any opposing party may submit a brief in opposition to the appeal, not to exceed 15 pages, within 20 days of receiving a copy of the appeal and accompanying brief. The opposing party may request leave to file a brief in excess of 15 pages for good cause shown. The brief in opposition shall specifically state the opposing party's reasons for supporting the hearing officer's determination, or for objecting to any part of the hearing officer's determination.

(d) *Service.* The appeal and all briefs shall be served on all parties and on the Docket Clerk.

(e) *Forwarding of the record.* Upon request by the Office of the Secretary, the hearing officer shall forward the record of the proceeding to the Secretary or the Secretary's designee.

(f) *Time extensions.* The Secretary, or designee, in his or her sole discretion, may extend the deadlines or page limitations set forth in paragraphs (b) and (c) of this section. The Secretary or designee may also permit the filing of additional briefs, in his or her sole discretion.

(g) *Personal appearance.* There is no right to appear personally before the Secretary or designee.

(h) *Interlocutory rulings.* There is no right to appeal any interlocutory ruling by the hearing officer, except as provided for in § 26.27.

(i) *Objection not raised before hearing officer.* In reviewing the determination or order, the Secretary, or designee, shall not consider any objection that was not raised before the hearing officer unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(j) *Evidence in the record.* The Secretary or designee shall consider only evidence contained in the record forwarded by the hearing officer. However, if any party demonstrates to the satisfaction of the Secretary or designee that additional evidence not presented at the hearing is material, and that there were reasonable grounds for the failure to present such evidence at the hearing, the Secretary or designee shall remand the matter to the hearing officer for reconsideration in light of the additional evidence.

(k) *Ex parte communications.* The prohibitions of ex parte communications in § 26.3 shall apply to contacts with the Secretary or the Secretary's designee.

(l) *Determination.* The Secretary or designee may affirm, modify, reverse, remand, reduce, compromise, or settle any determination made or action ordered in the initial determination or order. The Secretary or designee shall consider, and include in any final determination, such factors as may be set forth in applicable statutes or regulations.

(m) *Written determination.* Where a request for Secretarial review has been timely made, the Secretary, or designee, shall issue a written determination within 30 days after receipt of the request for review, and shall serve it upon the parties to the hearing and the hearing officer. The Secretary, or designee, may extend the time in which a written determination must be issued by an additional 60 days for good cause shown in a written justification issued to the parties. The written determination of the Secretary shall be final. If the Secretary, or designee, does not act upon the request for review of a determination within 90 days of service of the request, then the initial determination shall be the final agency action.

§ 26.27 Interlocutory rulings.

(a) *Interlocutory rulings by the hearing officer.* A party seeking review of an interlocutory ruling shall file a motion with the hearing officer within 10 days of the ruling requesting certification of the ruling for review by the Secretary, or in cases arising under 2 CFR part 2424, with the Debarring Official. Certification may be granted if the hearing officer believes that:

(1) It involves an important issue of law or policy as to which there is substantial ground for difference of opinion; and

(2) An immediate appeal from the order may materially advance the ultimate termination of the litigation.

(b) *Petition for review.* Any party may file a petition for review of an interlocutory ruling within 10 days of the hearing officer's determination regarding certification.

(c) *Secretarial review.* The Secretary, or designee, or Debarring Official shall review a certified ruling. The Secretary, designee, or Debarring Official has the discretion to grant or deny a petition for review from an uncertified ruling.

(d) *Continuation of hearing.* Unless otherwise ordered by the hearing officer or the Secretary, designee, or Debarring Official, the hearing shall proceed pending the determination of any interlocutory appeal, and the order or ruling of the hearing officer shall be effective pending review.

Subpart B—Hearings Pursuant to the Administrative Procedure Act

§ 26.28 Purpose and scope.

Unless otherwise specified in this title, the rules in this subpart B of this part apply to hearings that HUD is required by statute to conduct pursuant to the Administrative Procedure Act (5 U.S.C. 554 *et seq.*)

§ 26.29 Definitions.

The following definitions apply to subpart B of this part:

Complaint means the notice from HUD alleging violations of a HUD statute and/or regulation, citing the legal authority upon which it is issued, stating the relief HUD seeks, and informing a respondent of his or her right to submit a response to a designated office and to request an opportunity for a hearing before an Administrative Law Judge.

Docket Clerk means the Docket Clerk of the Office of Administrative Law Judges at the following address: 409 Third Street, SW., Second Floor, Washington, DC 20024.

Respondent, unless otherwise identified by other governing statute, rule, or regulation, is the party against whom the administrative action is taken.

Response means the written response to a complaint, admitting or denying the allegations in the complaint and setting forth any affirmative defense and any mitigating factors or extenuating circumstances. The response shall be submitted to the division of the Office of General Counsel that initiates the complaint or to such other office as may be designated in the complaint. A response is deemed a request for a hearing.

§ 26.30 Service and filing.

(a) *Filing.* Unless otherwise provided by statute, rule, or regulation, all documents shall be filed with the Docket Clerk. Filing may be by delivery, first class mail, overnight delivery, facsimile transmission, or electronic means; however, the ALJ may place reasonable limits on filing by facsimile transmission or electronic means. All documents shall clearly designate the docket number and title of the proceeding. Duplicate copies are not required unless ordered by the ALJ.

(b) *Service.* One copy of all documents filed with the Docket Clerk shall be served upon each party by the persons filing them and shall be accompanied by a certificate of service

stating how and when such service has been made. Service may be made by delivery, first class mail, overnight delivery, facsimile transmission, or electronic means; however, the ALJ may place reasonable limits on service by facsimile transmission or electronic means. Documents shall be served upon a party's address of residence or principal place of business, or, if the party is represented by counsel, upon counsel of record at the address of counsel. Service is complete when handed to the person or delivered to the person's office or residence and deposited in a conspicuous place. If service is by first-class mail, overnight delivery, facsimile transmission, or electronic means, service is complete upon deposit in the mail or upon electronic transmission.

§ 26.31 Time computations.

(a) *General.* In computing any period of time under subpart B of this part, the time period begins the day following the act, event, or default, and includes the last day of the period, unless the last day is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which case the time period includes the next business day. When the prescribed time period is 7 days or less, intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation.

(b) *Entry of orders.* In computing any time period involving the date of the issuance of an order or decision by an Administrative Law Judge, the date of issuance is the date the order or decision is served by the Docket Clerk.

(c) *Service by mail.* If a document is served by mail, 3 days shall be added to the time permitted for a response.

Administrative Law Judge

§ 26.32 Powers and duties of the Administrative Law Judge (ALJ).

The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made. The ALJ is authorized to:

(a) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(b) Continue or recess the hearing, in whole or in part, for a reasonable period of time;

(c) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(d) Administer oaths and affirmations;

(e) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;

(f) Rule on motions and other procedural matters;

(g) Regulate the scope and timing of discovery;

(h) Regulate the course of the hearing and the conduct of representatives and parties;

(i) Examine witnesses;

(j) Receive, rule on, exclude, or limit evidence;

(k) Upon motion of a party, take official notice of facts;

(l) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(m) Conduct any conference, argument, or hearing on motions in person or by telephone;

(n) Upon motion, except where mandated by statute, extend the time within which any act required by these rules must be performed where necessary to avoid prejudicing the public interest or the rights of the parties, or upon showing of good cause; and

(o) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under subpart B of this part.

§ 26.33 Ex parte communications.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 26.34 Sanctions.

(a) The ALJ may sanction a person, including any party or representative, for failing to comply with an order, rule, or procedure governing the proceeding; failing to prosecute or defend an action; or engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order compelling discovery, the ALJ may impose an appropriate sanction for such noncompliance, including, but not limited to, the following:

(1) Drawing an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deeming any matter about which an admission is requested to be admitted;

(3) Prohibiting the party failing to comply with the order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; or

(4) Striking any part of the pleadings or other submissions of the party failing to comply with the order.

(d) If a party fails to prosecute or defend an action brought under subpart B of this part, the ALJ may dismiss the action or may issue a decision against the non-prosecuting or defending party. Such decision of the ALJ shall constitute final agency action and shall not be appealable to the Secretary under § 26.52 of this part.

(e) The ALJ may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion.

§ 26.35 Disqualification of ALJ.

(a) An ALJ in a particular case may disqualify himself or herself.

(b) A party may file with the ALJ a motion for the ALJ's disqualification. The motion shall be accompanied by an affidavit alleging the grounds for disqualification.

(c) Upon the filing of a motion and affidavit, the ALJ shall proceed no further in the case until the matter of disqualification is resolved.

(d) If the ALJ does not withdraw from the proceedings, a written statement of his or her reasons for electing not to withdraw shall be incorporated into the record and the hearing shall proceed.

Parties

§ 26.36 Parties to the hearing.

(a) *General.* The parties to the hearing shall be the respondent and HUD.

(b) *Rights of parties.* Except as otherwise limited by subpart B of this part, all parties may:

(1) Be accompanied, represented, and advised by a representative;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery;

(4) Agree to stipulations of fact or law, which shall be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing, as permitted by the ALJ.

§ 26.37 Separation of functions.

No officer, employee, or agent of the Federal Government engaged in the

performance of investigative, conciliatory, or prosecutorial functions in connection with the proceeding shall, in that proceeding or any factually related proceeding under subpart B of this part, participate or advise in the decision of the Administrative Law Judge, except as a witness or counsel during the proceeding, or in its appellate review.

Prehearing Procedures

§ 26.38 Commencement of action.

Proceedings under subpart B of this part shall commence with the Government's filing of a complaint, as that term is defined in § 26.29, with the Docket Clerk. The respondent's response to the complaint shall be timely filed with the Docket Clerk and served upon the Government in accordance with the procedures set forth in the complaint. If the respondent fails to submit a response to the Docket Clerk, then the Government may file a motion for a default judgment in accordance with § 26.41.

§ 26.39 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party or sua sponte, the ALJ may schedule a prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may consider the following at a prehearing conference:

(1) Simplification of the issues;

(2) Stipulations of fact and of the authenticity, accuracy, and admissibility of documents;

(3) Submission of the case on briefs in lieu of an oral hearing;

(4) Limitation of the number of witnesses;

(5) The exchange of witness lists and of proposed exhibits;

(6) Discovery;

(7) The time and place for the hearing; and

(8) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

§ 26.40 Motions.

(a) *General.* All motions shall state the specific relief requested and the basis therefore and, except during a conference or the hearing, shall be in writing. Written motions shall be filed and served in accordance with § 26.30. Either party may submit a proposed order with any motion.

(b) *Response to motions.* Unless otherwise ordered by the ALJ, a response to a written motion may be filed within 10 days after service of the motion. A party failing to respond timely to a motion may be deemed to have waived any objection to the granting of the motion.

(c) *Motions for extensions.* Either party may file a motion for extension. At the discretion of the ALJ, a motion for an extension of time may be granted for good cause at any time, notwithstanding an objection or any reply to the motion, consistent with § 26.32(f). The ALJ may waive the requirements of this section as to motions for extensions of time or any page limits.

(d) *Right to reply.* The moving party shall have no right to reply, except as permitted by the ALJ.

(e) *Oral Argument.* Either party may request oral argument on any motion, but such argument shall be available at the sole discretion of the ALJ.

(f) *Motions for summary judgment.* (1) A party claiming relief or a party against whom relief is sought may timely move, with or without supporting affidavits, for summary judgment on all or part of the claim.

(2) Objections in the consideration of summary judgment motions or answers thereto based upon a failure to strictly comply with the provisions of Rule 56 of the Federal Rules of Civil Procedure may, at the discretion of the ALJ, be overruled.

(g) *Motions for dismissal.* When a motion to dismiss the proceeding is granted, the ALJ shall make and file a determination and order in accordance with the provisions of § 26.50.

§ 26.41 Default.

(a) *General.* The respondent may be found in default, upon motion, for failure to file a timely response to the Government's complaint. The motion shall include a copy of the complaint and a proposed default order, and shall be served upon all parties. The respondent shall have 10 days from such service to respond to the motion.

(b) *Default order.* The ALJ shall issue a decision on the motion within 15 days after the expiration of the time for filing a response to the default motion. If a default order is issued, it shall constitute the final agency action.

(c) *Effect of default.* A default shall constitute an admission of all facts alleged in the Government's complaint and a waiver of respondent's right to a hearing on such allegations. The penalty proposed in the complaint shall be set forth in the default order and shall be immediately due and payable by respondent without further proceedings.

Discovery

§ 26.42 Discovery.

(a) *General.* The parties are encouraged to engage in voluntary discovery procedures, which may commence at any time after an answer has been filed. Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. For good cause, the ALJ may order discovery of any matter relevant to the subject matter of the action. To be relevant, information need not be admissible at the hearing, if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. Each party shall bear its own expenses associated with discovery.

(b) *Discovery in Program Fraud Civil Remedies Actions.* (1) Upon receipt of a complaint, the defendant may, upon written request to the Office of General Counsel, review any relevant and material nonprivileged documents, including any exculpatory documents, that relate to the allegations set out in the complaint. Exculpatory information that is contained in a privileged document must be disclosed; however, the privileged document need not be provided.

(2) With the exception of the limited discovery permitted under paragraph (b)(1) of this section, unless agreed to by the parties, discovery shall be available only as ordered by the ALJ. The ALJ shall order only that discovery that he or she determines is necessary for the expeditious, fair, and reasonable consideration of the issues, is not unduly costly or burdensome, and will not unduly delay the proceeding. Discovery of privileged information shall not be permitted. The request for approval sent to the Attorney General from the General Counsel or designee, as described in 31 U.S.C. 3803(a)(2), is not discoverable under any circumstances. The ALJ may grant discovery subject to a protective order under § 26.44.

(c) *Authorized discovery.* The following types of discovery are authorized:

(1) *Requests for production of documents.* (i) Any party may serve upon any other party a written request to produce and permit the party making the request, or someone acting on the requestor's behalf, to inspect, copy, test, or sample any designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained—translated, if necessary, by

the respondent into reasonably usable form, or to inspect, copy, test, or sample any designated tangible things that constitute or contain matters within the scope of § 26.42(a) and which are in the possession, custody, or control of the party upon whom the request is served.

(ii) The request shall set forth, either by individual item or by category, the items to be inspected, and describe each with reasonable particularity. The request shall specify a reasonable time, place, and manner of making the inspection and performing the related acts. The request may specify the form or forms in which electronically stored information is to be produced.

(iii) The party upon whom the request is served shall serve a written response within 20 days after the service of the request. A shorter or longer time may be directed by the ALJ or, in the absence of such an order, agreed to in a written document by the parties, which shall be submitted to the ALJ in a timely manner. The response shall state, with respect to each item or category, whether inspection and related activities will be permitted as requested. If there are any objections to any requests, including objections to the requested form or forms for producing electronically stored information, the response shall state the reasons for such objections. If objection is made to part of an item or category, the part shall be specified and inspection permitted of the remaining parts. If objection is made to the requested format for producing electronically stored information—or if no format was specified in the request—the responding party must state the format it intends to use. The party submitting the request may move for an order under paragraph (e) of this section with respect to any objection to or other failure to respond to the request or any part thereof, or any failure to permit inspection as requested.

(iv) Unless the parties otherwise agree, or the ALJ otherwise orders:

(A) A party who produces documents for inspection shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the request;

(B) If a request does not specify the form or forms for producing electronically stored information, a responding party must produce the information in a format in which it is ordinarily maintained or in a format that is reasonably usable; and

(C) A party need not produce the same electronically stored information in more than one form.

(2) *Requests for admissions.* Any party may serve upon any other party a written request for the admission of the genuineness of any documents described in the request or of the truth of any relevant matters of fact. Copies of documents shall be delivered with the request unless copies have already been furnished. Each requested admission shall be considered admitted, unless, within 30 days after service of the request, or within such other time as the parties may agree to or the ALJ determines, the party from whom the admission is sought serves upon the party making the request either:

(i) A statement, which:

(A) Denies specifically the relevant matters for which an admission is requested, or sets forth in detail the reasons why the party can neither truthfully admit nor deny them;

(B) Fairly meets the substance of the requested admission, and when good faith requires that a party qualify an answer or deny only a part of the matter of which an admission is requested, the party specifies as much of it as is true and qualifies or denies the remainder; and

(C) Does not assert lack of information or knowledge as a reason for failure to admit or deny, unless the party states that the party has made reasonable inquiry, and that the information known or readily obtainable by the party is insufficient to enable the party to admit or deny; or

(ii) Written objections to a requested admission, which state the grounds for the objection and which object to a requested admission, if necessary, either in whole or in part, on the basis of privilege or relevance. Responses to the request for admission on matters to which objections have been made may be deferred until each objection is ruled upon, but if written objections are made only to a part of a request, a response to the remainder of the request shall be provided.

(iii) Any matter admitted under this rule is conclusively established unless the ALJ, on motion, permits withdrawal or amendment of the admission. Admissions obtained pursuant to this procedure may be used in evidence only for the purposes of the pending action. The use of obtained admissions as evidence is permitted to the same extent and subject to the same objections as other evidence.

(3) *Written interrogatories*—(i) *Service of written interrogatories.* Any party may serve upon any other party written interrogatories, not exceeding 25 in number, including all discrete subparts, unless additional interrogatories are agreed to by the parties or leave to serve additional interrogatories is granted by the ALJ.

(ii) *Response to interrogatories.* Within 20 days after service of the request, the party upon whom the interrogatories are served shall serve a written response, unless the parties agree in a written document submitted to the ALJ or the ALJ determines that a shorter or longer period is appropriate under the circumstances. The response shall specifically answer each interrogatory separately and fully in writing, unless it is objected to, in which event the objecting party shall state the reasons for objection with specificity. Any ground not stated in a timely objection is waived unless the party's failure to object is excused by the ALJ for good cause shown. If objection is made to only part of an interrogatory, the objectionable part shall be specified and the party shall answer to the extent the interrogatory is not objectionable.

(iii) *Option to produce business records.* Where the answer to an interrogatory may be derived or ascertained from the business records, including electronically stored information, of the party upon whom the interrogatory has been served or from an examination, audit, or inspection of such business records, including a compilation, abstract, or summary thereof, and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained and to afford to the party serving the interrogatory reasonable opportunity to examine, audit, or inspect such records and to make copies, compilations, abstracts, or summaries. A specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can the party served, the records from which the answer may be ascertained.

(4) *Depositions.* (i) A party may take the oral deposition of any person. Reasonable written notice of deposition shall be served upon the opposing party and the deponent. The attendance of a deponent may be compelled by subpoena where authorized by law or other order by the ALJ.

(ii) Each person testifying on oral deposition shall be placed under oath by the person before whom the deposition is taken. The deponent may be examined and cross-examined. The questions and the answers, together with all objections made, shall be recorded by the person before whom the deposition is to be taken or under that person's direction.

(iii) *Objections.* Objection may be made to questions or answers for any reason that would require the exclusion of the testimony under § 26.47 as if the witness were present and testifying at hearing. Objections shall be in short form, stating every ground for objection. Failure to object to any question or answer shall be considered a waiver of objection, unless the parties agree otherwise. Rulings on any objections shall be made by the ALJ at hearing, or at such other time as is requested by motion. The examination shall proceed, with the testimony being taken subject to the objections; a person may instruct a deponent not to answer only when necessary to preserve a privilege, to enforce a limitation directed by the ALJ, or to present a motion under § 26.44.

(iv) *Submission to deponent.* A transcript of the deposition shall be submitted to the deponent for examination and signature, unless submission is waived by the deponent and the parties. Any changes in form or substance that the deponent desires to make shall be entered upon the transcript by the person before whom the deposition was taken, with a statement of reasons given by the deponent for making them. The transcript shall then be signed by the deponent, unless the parties by stipulation waive the signing or the deponent is ill, cannot be found, or refuses to sign. If the transcript is not signed, the person before whom the deposition was taken shall sign it and state on the record the reason that it is not signed by the deponent.

(v) *Certification and filing.* The person before whom the deposition was taken shall make a certification on the transcript as to its accuracy. Interested parties shall make their own arrangements with the person recording the testimony for copies of the testimony and the exhibits.

(vi) *Deposition as evidence.* Subject to appropriate rulings by the ALJ on objections, the deposition or any part may be introduced into evidence for any purpose if the deponent is unavailable. Only that part of a deposition that is received in evidence at hearing shall constitute a part of the record in the proceeding upon which a decision may be based. Nothing in this rule is intended to limit the use of a deposition for impeachment purposes.

(vii) *Payment of fees.* Fees shall be paid by the person upon whose application the deposition is taken.

(d) *Supplementation of responses.* A party who has responded to a request for discovery by providing a response is under a duty to timely amend any prior response to an interrogatory, request for production, or request for admission if so ordered by the ALJ, or if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to all other parties during the discovery process or in writing.

(e) *Motions to compel.* (1) In connection with any discovery procedure, by motion addressed to the ALJ and upon a showing of a good faith attempt to resolve the issue without the ALJ's intervention, either party may file a motion to compel a response with respect to any objection or other failure to respond to the discovery requested or to any part thereof, or any failure to respond as specifically requested. An evasive or incomplete answer to a request for discovery is treated as a failure to answer.

(2) The motion shall describe the information sought, cite the opposing party's objection, and provide arguments supporting the motion.

(3) The opposing party may file a response to the motion, including a request for a protective order in accordance with § 26.44.

(4) Orders compelling discovery shall be issued only where such discovery will not compel the disclosure of privileged information, unduly delay the hearing, or result in prejudice to the public interest or the rights of the parties, and upon a showing of good cause.

(5) A party need not provide discovery of electronically stored information from sources that the party identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery, the party from whom discovery is sought must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the ALJ may nonetheless order discovery from such sources if the requesting party shows good cause or, when the party's refusal to provide the information sought is solely due to undue expense, the party seeking the discovery agrees to bear the expense associated with the request.

(f) *Refusal to honor discovery order.* When a party refuses to honor a discovery order, the ALJ may issue such orders in regard to the refusal as justice shall require, including the imposition of sanctions pursuant to § 26.34.

§ 26.43 Subpoenas.

(a) *General.* Upon written request of a party, the ALJ may issue a subpoena requiring the attendance of a witness at a deposition or hearing, and/or the production of documents. The request shall specify any documents to be produced and shall list the names and addresses of the witnesses.

(b) *Time of request.* A request for a subpoena in aid of discovery shall be filed in time to permit the conclusion of discovery 15 days before the date fixed for the hearing. A request for a subpoena to testify at the hearing shall be filed at least 3 days prior to the hearing, unless otherwise allowed by the ALJ for good cause shown.

(c) *Content.* The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(d) *Service and fees.* Subpoenas shall be served, and fees and costs paid to subpoenaed witnesses, in accordance with Rule 45(b)(1) of the Federal Rules of Civil Procedure.

(e) *Motion to quash.* The individual to whom the subpoena is directed or a party may file a motion to quash the subpoena within 10 days after service, or on or before the time specified in the subpoena for compliance if it is less than 10 days after service.

§ 26.44 Protective orders.

(a) A party, a prospective witness, or a deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) Protective orders may be issued by an ALJ if the ALJ determines such an order is necessary to protect a party or other person from annoyance, embarrassment, oppression, or undue burden or expense because:

(1) The discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;

(2) The party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or

(3) The burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

Hearings

§ 26.45 General.

(a) *Time of hearing.* The hearing shall commence not later than 90 days following the date of the Government's filing of the complaint and response with the Chief Docket Clerk under § 26.38, unless the time is extended for

good cause. The ALJ shall provide written notice to all parties of the reasons for any extension of time.

(b) *Location of hearing.* The hearing shall be held in a place most convenient for the respondent and witnesses, or in such other place as may be agreed upon by the parties and the ALJ.

(c) *Notice of hearing.* The ALJ shall issue a notice of hearing to all parties specifying the time and location of the hearing, the matters of fact and law to be heard, the legal authority under which the hearing is to be held, a description of the procedures for the conduct of the hearing, and such other matters as the ALJ determines to be appropriate.

(d) *Exceptions for Program Fraud Civil Remedies Act matters.* For Program Fraud Civil Remedies actions, the hearing is commenced by the issuance of a notice of hearing and order by the ALJ, as set forth in 31 U.S.C. 3803(d)(2)(B). Hearings for Program Fraud Civil Remedies Act matters shall be located in accordance with 31 U.S.C. 3803(g)(4).

(e) *Burden and standard of proof.* HUD shall prove the respondent's liability and any aggravating factors by a preponderance of the evidence. Respondent shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(f) *Public hearings.* Unless otherwise ordered by the ALJ for good cause shown, the hearing shall be open to the public.

§ 26.46 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. In order to be admissible, any written statement must be provided to all other parties along with the last known address of the witness, in a manner that allows sufficient time for other parties to subpoena the witness for cross-examination at the hearing.

§ 26.47 Evidence.

The ALJ shall admit any relevant oral or documentary evidence that is not privileged. Unless otherwise provided for in this part, the Federal Rules of Evidence shall provide guidance to the ALJ's evidentiary ruling, but shall not be binding. Parties may object to clearly irrelevant material, but technical and hearsay objections to testimony as used in a court of law will not be sustained. The ALJ may, however, exclude evidence if its probative value is substantially outweighed by confusion of the issues, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

§ 26.48 Posthearing briefs.

Posthearing briefs shall be filed only upon order by the ALJ.

§ 26.49 The record.

The hearing will be recorded and transcribed by a reporter designated by the Department under the supervision of the ALJ. The parties and the public, at their own expense, may obtain copies of transcripts from the reporter. A copy of the transcript shall be made available at cost to the parties upon request. The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary or designee.

§ 26.50 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the relief granted. The ALJ's initial decision shall not become effective unless it becomes or is incorporated into final agency action in accordance with §§ 26.50(c) or 26.52(l).

(b) The ALJ shall serve the initial decision on all parties within 60 days after either the close of the record or the expiration of time permitted for submission of posthearing briefs, whichever is later. The ALJ may extend the 60-day period for serving the initial decision in writing for good cause. The initial decision shall inform the parties that, if provided for and consistent with Departmental regulations, any party may request, in writing, Secretarial review of the determination within 30 days after the ALJ issues the initial decision, in accordance with § 26.52 of this part. The determination shall include the mailing address, facsimile number, and electronic submission information to which the request for Secretarial review should be sent. A request for Secretarial review may be made by mail, delivery, facsimile, or electronic submission.

(c) If no appeal is timely filed with the Secretary or designee, the initial decision shall become the final agency action.

§ 26.51 Interlocutory rulings.

(a) *Interlocutory rulings by the ALJ.* A party seeking review of an interlocutory ruling shall file a motion with the ALJ within 10 days of the ruling requesting certification of the ruling for review by the Secretary. Certification may be granted if the ALJ believes that:

(1) It involves an important issue of law or policy as to which there is substantial ground for difference of opinion; and

(2) An immediate appeal from the order may materially advance the ultimate termination of the litigation.

(b) *Petition for review.* Any party may file a petition for review of an interlocutory ruling within 10 days of the ALJ's determination regarding certification.

(c) *Secretarial review.* The Secretary, or designee, shall review a certified ruling. The Secretary, or designee, has the discretion to grant or deny a petition for review from an uncertified ruling.

(d) *Continuation of hearing.* Unless otherwise ordered by the ALJ or the Secretary, or designee, the hearing shall proceed pending the determination of any interlocutory appeal, and the order or ruling of the ALJ shall be effective pending review.

§ 26.52 Appeal to the Secretary.

(a) *General.* Either party may file with the Secretary an appeal within 30 days after the date that the ALJ issues an initial decision. The Secretary or the Secretary's designee may extend the 30-day period in his or her sole discretion, for good cause.

(b) *Brief in support of appeal.* The appeal shall be accompanied by a written brief, not to exceed 15 pages, specifically identifying the party's objections to the initial decision or order of the ALJ and the party's supporting reasons for any objections. The appealing party may request leave to file a brief in excess of 15 pages for good cause shown. Alternative proposed findings and conclusions, if any, may be appended as an exhibit.

(c) *Briefs in opposition.* Any opposing party may submit a brief in opposition to the appeal, not to exceed 15 pages, within 20 days of the date a copy of the appeal and accompanying brief were received. The opposing party may request leave to file a brief in excess of 15 pages for good cause shown. The brief in opposition shall specifically state the opposing party's reasons for supporting the ALJ's determination or taking exceptions to any part of the ALJ's determination.

(d) *Extensions and additional briefs.* The Secretary or Secretary's designee may extend the deadlines or page limitations set forth in paragraphs (b), (c), and (d) of this section, in his or her sole discretion. The Secretary may also permit the filing of additional briefs, in his or her sole discretion.

(e) *Forwarding of the record.* Upon request by the Office of the Secretary, the ALJ shall forward the record of the proceeding to the Secretary or designee.

(f) *Personal appearance.* There is no right to appear personally before the Secretary or designee.

(g) *ALJ decisions upon failure to prosecute or defend.* There is no right to appeal any decision issued by an ALJ in accordance with § 26.37(d) of this part.

(h) *Objections not raised before ALJ.* In reviewing the initial decision, the Secretary or designee shall not consider any objection that was not raised before the ALJ, unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) *Evidence considered.* The Secretary or designee shall consider only evidence contained in the record forwarded by the ALJ. However, if any party demonstrates to the satisfaction of the Secretary or designee that additional evidence not presented at the hearing is material and that there were reasonable grounds for the failure to present such evidence at the hearing, the Secretary or designee shall remand the matter to the ALJ for reconsideration in light of the additional evidence.

(j) *Ex parte communications.* The prohibitions of ex parte communications in § 26.33 shall apply to contacts with the Secretary or designee.

(k) *Relief.* The Secretary or designee may affirm, modify, reduce, reverse, compromise, remand, or settle any relief granted in the initial decision. The Secretary or designee shall consider, and include in any final determination, such factors as may be set forth in applicable statutes or regulations.

(l) *Decision*—(1) *Generally.* Where a Secretarial appeal has been timely made, the Secretary, or designee, shall issue a written determination within 30 days after receipt of the brief in opposition, if any, and shall serve it upon the parties to the hearing. The Secretary, or designee, may extend the time in which a written determination must be issued by an additional 60 days for good cause shown in a written justification issued to the parties. The written decision of the Secretary shall be the final agency action. If the Secretary, or designee, does not act upon the appeal of an initial decision within 90 days of service of the appeal, then the initial determination shall be the final agency action.

(2) *Exception for cases brought under the Program Fraud Civil Remedies Act.* Where a Secretarial appeal has been timely made in a case brought under the Program Fraud Civil Remedies Act, the Secretary, or designee, shall issue a written determination within 30 days after receipt of appeal and shall serve it upon the parties to the hearing. The written decision of the Secretary shall be the final agency action. If the Secretary, or designee, does not act upon the appeal of an initial decision within 30 days of service of the appeal, the initial decision shall become final and the Respondent will be served with a statement describing the right to seek judicial review, if any.

§ 26.53 Exhaustion of administrative remedies.

In order to fulfill the requirement of exhausting administrative remedies, a party must seek Secretarial review under § 26.52 prior to seeking judicial review of any initial decision issued under subpart B of this part.

§ 26.54 Judicial review.

Judicial review shall be available in accordance with applicable statutory procedures and the procedures of the appropriate federal court.

§ 26.55 Collection of civil penalties and assessments.

Collection of civil penalties and assessments shall be in accordance with applicable statutory provisions.

§ 26.56 Right to administrative offset.

The amount of any penalty or assessment that has become final under §§ 26.50 or 26.52, or for which a judgment has been entered after action under §§ 26.54 or 26.55, or agreed upon in a compromise or settlement among the parties, may be collected by administrative offset under 31 U.S.C. 3716 or other applicable law. In Program Fraud Civil Remedies Act matters, an administrative offset may not be collected against a refund of an overpayment of federal taxes then or later owing by the United States to the Respondent.

Dated: August 13, 2008.

Roy A. Bernardi,

Deputy Secretary.

[FR Doc. E8–20761 Filed 9–5–08; 8:45 am]

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Federal Register

Monday,
September 8, 2008

Part IV

Department of Housing and Urban Development

24 CFR Part 28

Revisions to the Regulations Implementing the Program Fraud Civil Remedies Act of 1986; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 28

[Docket No. FR–5085–P–01]

RIN 2501–AD25

Revisions to the Regulations Implementing the Program Fraud Civil Remedies Act of 1986

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend HUD's regulations implementing the Program Fraud Civil Remedies Act of 1986 (PFCRA), which were codified in 1996 and were amended in 2003 to include inflation adjustments. The purpose of this proposed rule is to more closely conform the PFCRA regulations with the PFCRA statutory language, to incorporate additional definitions into the PFCRA regulations, and to add an additional item to the list of factors the Secretary shall consider in determining the amount of penalties and assessments to be imposed.

DATES: *Comment Due Date:* November 7, 2008.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dane Narode, Acting Associate General Counsel, Office of Program Enforcement, Department of Housing and Urban Development, 1250 Maryland Avenue, Suite 200, Washington, DC 20024–0500; telephone number 202–708–2350 (this is not a toll-free number); e-mail address *Dane.M.Narode@hud.gov.* Hearing- or speech-impaired individuals may access the voice telephone number listed above by calling the toll-free Federal Information Relay Service during working hours at 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

On June 24, 1988 (53 FR 24000), HUD published its regulations implementing the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. 3801) (PFCRA). PFCRA established administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to HUD or its agents. HUD's regulations implementing PFCRA are located at 24 CFR part 28. On September 24, 1996 (61 FR 50208), HUD issued a final rule further streamlining the PFCRA regulations at part 28.

II. This Proposed Rule

This proposed rule would more closely conform both § 28.5 (''Definitions'') and § 28.10 (''Basis for civil penalties and assessments'') to the PFCRA statutory provisions. A definition of ''reasonable prospect'' would be included in § 28.5 to explain that the Reviewing Official will use limited information available in HUD's Report of Investigation to determine whether allocating HUD's resources to a particular action is appropriate. Also, a definition of ''Ability to pay'' would be included in § 28.5 to clarify that a factor in determining amounts of penalties and assessments will be based on an assessment of the respondent's resources available presently and prospectively, from which the Department could ultimately recover the total award. The definition would also allow for the consideration of respondent's resources to be based on historical evidence. The proposed rule would also modify § 28.25 (''Complaint'') so that the provisions for methods of complaint transmittal more closely conform to PFCRA and to give the same meaning to the term ''deliver'' that it has in PFCRA. This section would require both parties to preserve documents upon issuance of the complaint for the Department, and receipt of the complaint for the respondent. Additionally, this section and § 28.30 would be revised to provide for the filing of the complaint and answer directly with the Office of Administrative Law Judges, in accordance with the specified provisions of § 26.30 of this title.

Furthermore, the proposed rule would revise § 28.35 to remove the disclosure of documents regulation from part 28. The disclosure of documents regulation would, under a separate proposed rule regarding HUD's hearing procedures, be moved to part 26 (''Hearing Procedures''). Under this proposed rule, § 28.35 would incorporate the substance of the regulation on the statute of limitations for PFCRA hearings, which would be moved from part 26 under the separate proposed rule.

Finally, the proposed rule would add ''ability to pay'' to § 28.40 (''Hearings'') as an additional factor to be considered in determining the amount of penalties and assessments; the factor has been added to the definitions at § 28.5, as discussed above.

III. Small Business Concerns Related to Board Enforcement Actions

With respect to enforcement actions undertaken pursuant to this proposed rule, HUD is cognizant that section 222 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) requires the Small Business and Agriculture

Regulatory Enforcement Ombudsman to ''work with each agency with regulatory authority over small businesses to ensure that small business concerns that receive or are subject to an audit, on-site inspection, compliance assistance effort, or other enforcement related communication or contact by agency personnel are provided with a means to comment on the enforcement activity conducted by this personnel.'' To implement this statutory provision, the Small Business Administration has requested that federal agencies include the following language on agency publications and notices that are provided to small business concerns at the time the enforcement action is undertaken. The language is as follows:

Your Comments Are Important

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of [insert agency name], you will find the necessary comment forms at *www.sba.gov/ombudsman* or call 1–888–REG–FAIR (1–888–734–3247).

In accordance with its notice describing HUD's actions on the implementation of SBREFA, which was published on May 21, 1998 (63 FR 28214), HUD will include the language cited above on notices implementing enforcement actions, to ensure that small entities have the full means to comment on the enforcement activity conducted by HUD.

IV. Findings and Certifications

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This proposed rule would revise definitions and usages of terms to conform more closely with those of the governing statute, and would add ''ability to pay'' as a factor to be considered in determining penalty and assessment amounts. These revisions impose no significant economic impact on a substantial number of small entities. Therefore, the undersigned certifies that this rule will not have a significant impact on a substantial number of small entities.

Notwithstanding HUD's view that this rule will not have a significant effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Environmental Impact

This proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction; or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of Section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531–1538) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This proposed rule does not impose any federal mandates on any state, local, or tribal government or the private sector within the meaning of UMRA.

List of Subjects for 24 CFR Part 28

Administrative practice and procedure, Claims, Fraud, Penalties.

Accordingly, for the reasons discussed in the preamble, HUD proposes to amend 24 CFR part 28 as follows:

PART 28—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

1. The authority citation for 24 CFR part 28 is revised to read as follows:

Authority: 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812; 42 U.S.C. 3535(d).

2. Revise § 28.1(b) to read as follows:

§ 28.1 Purpose.

* * * * *

(b) Specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments. Hearings under this part shall be conducted in accordance with the Administrative Procedure Act pursuant to part 26, subpart B, of this chapter.

3. Revise § 28.5 to read as follows:

§ 28.5 Definitions.

(a) The terms *ALJ* and *HUD* are defined in 24 CFR part 5.

(b) The terms *Claim, Knows or has reason to know, Person, Reviewing Official,* and *Statement* have the same meanings as defined in 31 U.S.C. § 3801.

(c) *Ability to pay* is determined based on an assessment of the respondent's resources available both presently and prospectively from which the Department could ultimately recover the total award, which may be predicted based on historical evidence.

(d) *Benefit* means anything of value, including, but not limited to, any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan insurance or guarantee.

(e) *Respondent* means any person alleged to be liable for a civil penalty or assessment under § 28.25.

(f) The *reasonable prospect of collecting an appropriate amount of penalties and assessments* is determined based on a generalized assessment made by a Reviewing Official based on the limited information available in the Report of Investigation for purposes of determining whether the allocation of HUD's resources to any particular action is appropriate. This assessment is not the same as the assessment made when determining ability to pay, nor is the reasonable prospect of collecting a factor to be considered in determining the amount of any penalty or assessment in any particular case.

(g) *Report of Investigation* means a report containing the findings and conclusions of a Program Fraud Civil Remedies Act investigation by the Inspector General or his or her designee as described in § 28.15.

4. Revise § 28.10(a)(1) and (b)(1) to read as follows:

§ 28.10 Basis for civil penalties and assessments.

(a) *Claims.* (1) A civil penalty of up to $7,500 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a claim that the person knows or has reason to know:

(i) Is false, fictitious, or fraudulent;

(ii) Includes or is supported by a written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes or is supported by any written statement that:

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of the omission; and

(C) Is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed.

* * * * *

(b) *Statements.* (1) A civil penalty of up to $7,500 may be imposed upon any person who makes, presents, or submits, or causes to be made, presented, or submitted, a written statement that:

(i) The person knows or has reason to know:

(A) Asserts a material fact which is false, fictitious, or fraudulent; or

(B) (*1*) Omits a material fact; and

(*2*) Is false, fictitious, or fraudulent as a result of such omission;

(ii) In the case of a statement described in paragraph (b)(1)(i)(B) of this section, is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact; and

(iii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement.

* * * * *

5. Revise § 28.20 to read as follows:

§ 28.20 Request for approval by the Department of Justice.

(a) If the General Counsel or designee determines that the Report of Investigation supports an action under this part, he or she must submit a written request to the Department of Justice for approval to issue a complaint under § 28.25.

(b) The request shall include a description of the claims or statements at issue; the evidence supporting the allegations; an estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of § 28.10; any exculpatory or mitigating circumstances that may relate to the claims or statements; and a statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

6. Revise § 28.25 to read as follows:

§ 28.25 Complaint.

(a) *General.* Upon obtaining approval from the Department of Justice, the General Counsel or designee may issue a complaint to the respondent. The complaint shall be mailed, by registered or certified mail, or shall be delivered through such other means by which delivery may be confirmed. The complaint shall also be filed simultaneously with the Office of Administrative Law Judges in accordance with § 26.30(a) of this chapter.

(b) *Complaint.* The complaint shall include:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the claims or statements at issue, and the reasons why liability arises from those claims or statements;

(2) A statement that the required approval to issue the complaint was received from the Department of Justice as required by 24 CFR 28.20;

(3) The amount of penalties and assessments for which the respondent may be held liable;

(4) A statement that the respondent may request a hearing by submitting a written response to the complaint;

(5) The addresses to which a response must be sent in accordance with § 26.38 of this title; and

(6) A statement that failure to submit an answer within 30 days of receipt of the complaint may result in the imposition of the maximum amount of penalties and assessments sought without right of appeal.

(c) *Parts 26 and 28.* A copy of this part 28 and part 26, subpart B of this chapter shall be included with the complaint.

(d) *Obligation to preserve documents.* Upon receipt of the complaint, the respondent is required to preserve and maintain all documents and data, including electronically stored data, within their possession or control that may relate to the allegations in the complaint. The Department shall also preserve such documents or data upon the issuance of the complaint.

7. Revise § 28.30 to read as follows:

§ 28.30 Response.

(a) The respondent may file a written response to the complaint in accordance with § 26.30 of this title within 30 days of service of the complaint. The response shall be deemed to be a request for a hearing. The response must include the admission or denial of each allegation of liability made in the complaint; any defense on which the respondent intends to rely; any reasons why the penalties and assessments should be less than the amount set forth in the complaint; and the name, address, and telephone number of the person who will act as the respondent's representative, if any.

(b) *Failure to respond.* If no response is submitted, HUD may file a motion for default judgment in accordance with § 26.41 of this chapter.

8. Revise § 28.35 to read as follows:

§ 28.35 Statute of limitations.

The statute of limitations for commencing hearings under this part shall be tolled:

(a) If the hearing is commenced in accordance with 31 U.S.C. 3803(d)(2)(B) within 6 years after the date on which the claim or statement is made; or

(b) If the parties agree to such tolling.

9. Amend § 28.40 as follows:

a. Revise paragraphs (a) and (b);

b. Redesignate paragraph (b)(17) as (b)(18);

c. Add a new paragraph (b)(17); and

d. Revise newly designated paragraph (b)(18).

§ 28.40 Hearings.

(a) *General.* Hearings under this part shall be conducted in accordance with the procedures in part 26, subpart B, of this chapter, governing actions in accordance with the Administrative Procedure Act.

(b) *Factors to consider in determining amount of penalties and assessments.* In determining an appropriate amount of civil penalties and assessments, the ALJ and, upon appeal, the Secretary or designee, shall consider and state in his or her opinion any mitigating or aggravating circumstances. Because of the intangible costs of fraud, the expense of investigating fraudulent conduct, and the need for deterrence, ordinarily twice the amount of the claim as alleged by the government, and a significant civil penalty, should be imposed. The amount of penalties and assessments imposed shall be based on the ALJ's and the Secretary's or designee's consideration of evidence in support of one or more of the following factors:

(17) The respondent's ability to pay, and

(18) Any other factors that in any given case may mitigate or aggravate the seriousness of the false claim or statement.

* * * * *

Dated: July 28, 2008.

Roy A. Bernardi,

Deputy Secretary.

[FR Doc. E8–20760 Filed 9–5–08; 8:45 am]

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Monday,
September 8, 2008

Part V

Department of Labor

Mine Safety and Health Administration

30 CFR Parts 56, 57, and 66

Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance; Proposed Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, and 66

[1219–AB41]

Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Proposed rule.

SUMMARY: The proposed rule would replace the existing metal and nonmetal standards for the possession and use of intoxicating beverages and narcotics and establish a standard for all mines. The proposed rule would designate the substances that cannot be possessed on mine property or used while performing safety-sensitive job duties, except when used according to a valid prescription. Mine operators would be required to establish an alcohol- and drug-free mine program, which includes a written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive job duties and their supervisors, and referrals to assistance for miners who violate the policy. The proposed rule would also require those who violate the prohibitions to be removed from the performance of safety-sensitive job duties until they complete the recommended treatment and their alcohol- and drug-free status is confirmed by a return-to-duty test.

DATES: All comments must be received by midnight eastern standard time on October 8, 2008.

ADDRESSES: Comments must be clearly identified with ''RIN 1219–AB41'' and may be sent by any of the following methods:

(1) *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Electronic mail: zzMSHA-comments@dol.gov.* Include ''RIN 1219–AB41'' in the subject line of the message.

(3) *Facsimile:* 202–693–9441. Include ''RIN 1219–AB41'' in the subject line of the message.

(4) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939.

(5) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

Comments can be accessed electronically at *http://www.msha.gov* under the *Rules and Regs* link. MSHA will post all comments on the Internet without change, including any personal information provided. Comments may also be reviewed at the Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

MSHA maintains a list that enables subscribers to receive e-mail notification when rulemaking documents are published in the **Federal Register**. To subscribe, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

Information Collection Requirements: Comments concerning the information collection requirements of this proposed rule must be clearly identified with ''RIN 1219–AB41'' and sent to both the Office of Management and Budget (OMB) and MSHA. Comments to OMB may be sent by mail addressed to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for MSHA. Comments to MSHA may be transmitted either electronically to *zzMSHA-comments@dol.gov,* by facsimile to (202) 693–9441, or by regular mail, hand delivery, or courier to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939.

FOR FURTHER INFORMATION CONTACT: Elena Carr at *carr.elena@dol.gov* (E-mail), 202–693–5959 (Voice).

SUPPLEMENTARY INFORMATION: The outline of this proposal is as follows:

I. Introduction
II. Background
III. Discussion of the Proposed Rule
  A. Nature, Extent, and Impact of the Problem
  B. Effective Strategies for Addressing Alcohol and Drug Problems in Mining
  C. Basis of Proposal
IV. Section-by-Section Discussion
V. Executive Order 12866
  A. Population at Risk
  B. Benefits
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VI. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act
  A. Definition of a Small Mine
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  A. The Unfunded Mandates Reform Act of 1995
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  D. Executive Order 12988: Civil Justice Reform
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  F. Executive Order 13132: Federalism
  G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
  H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking
IX. Proposed Rule

I. Introduction

The Mine Safety and Health Administration's (MSHA) mission is to administer and enforce the provisions of the Federal Mine Safety and Health Act of 1977 (Mine Act), as amended by the Mine Improvement and New Emergency Response Act of 2006 (MINER Act), and includes promoting improved safety and health conditions in the nation's mines. Under the Mine Act, MSHA is required to develop improved mandatory safety and health standards for coal and metal/nonmetal mines. The misuse of alcohol and/or drugs is a risk to miner safety. Because mining is inherently dangerous, MSHA is proposing a standard to address this risk.

Currently, MSHA's mine accident investigations do not routinely include inquiries into the use of alcohol or drugs as contributing factors. Consequently, there may have been accidents in which alcohol or drugs were involved but were not reported to inspectors or identified during MSHA investigations. A preliminary review of fatal and non-fatal mine accident records revealed a number of instances in which alcohol or drugs or drug paraphernalia were found or reported, or where the post-accident toxicology screen revealed the presence of alcohol or drugs.

The U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration's (SAMHSA) 2006 National Survey on Drug Use and Health [1] reports that in 2006, of the 17.9 million illicit drug [2] users age 18 and

[1] The 2006 National Survey on Drug Use and Health (NSDUH) is the annual survey and primary source of information on the use of illicit drugs, alcohol, and tobacco in the civilian, non-institutionalized population of the United States aged 12 years or older.

[2] The survey defined current illicit drug use as the non-medical use of marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants

over, 13.4 million (74.9 percent) were employed.[3] Similarly, among 54 million adult binge drinkers, 42.9 million (79.4 percent) were employed, and among 16.3 million persons reporting heavy alcohol use, 12.9 million (79.2 percent) were employed.[4] Also, in 2006, of the 20.6 million adults classified with substance dependence or abuse, 12.7 million (61.5 percent) were employed full-time.[5] Furthermore, among the U.S. working age population (ages 18–64) diagnosed with a substance use disorder, 62.7 percent were employed full-time.[6]

According to a 1998 analysis of available toxicology reports across a variety of occupations and within different industries, the Bureau of Labor Statistics (BLS) estimated that as many as one in five workplace fatalities had a positive test for alcohol or drugs.[7] BLS reported that alcohol was the substance found most often, appearing in 48 percent of positive reports.[8]

SAMHSA's June 2007 *Worker Substance Use and Workplace Policies and Programs* Report [9] shows alcohol and other drug use and abuse by standard occupational and industry classifications. Illicit drug use was reported at 15.1 percent and heavy alcohol use was reported at 17.8 percent among full-time workers aged 18–64 in the construction, trade, and excavation occupational group.[10] The data also show that in the mining [11] industry, 13.3 percent of full-time miners were heavy alcohol users and 7.3 percent admitted that they used illicit drugs within the past month. This does not mean that those surveyed admitted to either being under the influence or having used alcohol or drugs at work or immediately prior to work. However, the statistics do suggest a cause for employer concern since there are no guarantees that those who drink heavily or abuse drugs will constrain such behaviors, which have the potential to seriously jeopardize mine safety, to off-duty hours.

Using alcohol and/or drugs can affect a miner's coordination and judgment significantly at a time when he or she needs to be alert, aware, and capable of performing tasks where there is substantial risk of injury to oneself or others. Even prescription medications may affect a miner's perception and reaction time. Mining is a complicated and hazardous occupation, and a clear focus on the work at hand is a crucial component of mine safety. Miners under the influence of alcohol and/or prohibited drugs endanger themselves as well as their co-workers. This is of particular concern since many fatal and non-fatal mining accidents involve the operation of some type of equipment, tool, or machinery.

A number of mine operators recognize this problem, and require applicants for employment to submit to and pass a pre-employment drug screening. At the Keeping America's Mines Alcohol and Drug Free summit held on December 18, 2004, some mine operators stated that a number of job applicants are unable to pass the initial drug screen.[12]

To the extent that misuse of alcohol and/or abuse of drugs by miners is prevalent in the community, as evidenced by the survey data referenced above, and given the inherent risks in mining that would only be compounded by the dangers of alcohol or drug use at the worksite, MSHA has determined the need to protect the safety of all miners by issuing a rule that prohibits miners from using, possessing, or being under the influence of alcohol or drugs when performing safety-sensitive job duties.

II. Background

The Mine Act [13] expressly states that the health and safety of the miner is the first priority and concern of all in the coal or other mining industry. The prevention of deaths and serious injuries from unsafe and unhealthful conditions and practices in the coal or other mines continues to be one of the many priorities of the Act. Section 101(a) of the Act authorizes the Secretary of Labor to develop, promulgate, and revise as may be appropriate improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines.

The presence and use of intoxicating beverages and narcotics is currently prohibited in both the surface and underground metal and nonmetal mine regulations found at 30 CFR 56.20001 and 57.20001. The current regulation states: ''Intoxicating beverages and narcotics shall not be permitted or used in or around mines. Persons under the influence of alcohol or narcotics shall not be permitted on the job.'' The regulations do not contain a similar requirement for coal mines.

During the 30 years from 1978 to early 2008, a total of 270 citations were issued for violations of these alcohol and drug prohibitions. Of these, 242 (89.6 percent) were at surface mines and 28 (10.4 percent) were at underground mines. Between January 1, 2000 and June 30, 2005, penalties were assessed for 75 violations of section 56.20001 and for three violations of section 57.20001 of the regulations.

Since the late 1980s, a proactive federal government has implemented a number of programs aimed at reducing the use of alcohol and drugs in the workplace. The Anti-Drug Abuse Act of 1986 (Pub. L. 99–570), directed the Secretary of Labor to initiate efforts to address the issue. Subsequently in 1986, Executive Order 12564, Drug-Free Federal Workplace, established federal drug-free workplaces by making it a condition of employment for all federal employees to refrain from using illegal drugs. The Drug-Free Workplace Act of 1988, 41 U.S.C. 701, *et seq.*, required federal contractors and grantees to have drug-free workplaces, and the Drug-Free Workplace Act of 1998, 15 U.S.C. 654, established grant programs that assist small businesses in developing drug-free workplace programs. To protect public safety, the Omnibus Transportation Employee Testing Act of 1991, Public Law 102–143, required transportation industry employers to conduct alcohol- and drug-testing for employees in ''safety-sensitive'' positions, creating a model that many non-regulated employers now follow.[14]

or prescription-type drugs. Non-medical use is defined as the use of prescription-type drugs not prescribed for the respondent by a physician or used only for the experience or feeling they caused. Non-medical use of any prescription-type pain reliever, sedative, stimulant, or tranquilizer does not include over-the counter drugs. Non-medical use of stimulants includes methamphetamine use.

[3] Substance Abuse and Mental Health Services Administration (2007). *Results from the 2006 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H–32, DHHS Publication No. SMA 07–4293). Rockville, MD.

[4] Ibid.

[5] Ibid.

[6] Ibid.

[7] Weber, W., and Cox, C. ''Work-Related Fatal Injuries in 1998,'' Compensation and Working Conditions, Spring 2001, pp. 27–29.

[8] Ibid.

[9] Substance Abuse and Mental Health Services Administration (2007). *The Worker Substance Use and Workplace Policies and Programs* Report presents findings on substance abuse among workers and on workplace drug policy and programs from the 2002, 2003, and 2004 National Surveys on Drug Use and Health. (Office of Applied Studies, Analytic Series: A–29.)

[10] The Standard Occupation System categorizes occupations into 21 groups. The Construction Trades and Extraction Workers group includes mining.

[11] The NAICS, which replaced the Standard Industry Classification (SIC), categorizes all industries into 19 major groups and is used to classify industries in the *Report.*

[12] This summit was hosted by the states of Kentucky, Virginia and West Virginia and by the U.S. Department of Labor, Mine Safety and Health Administration.

[13] Public Law 91–173, as amended by Public Law 95–164.

[14] The U.S. Department of Transportation's drug-testing regulations (49 CFR part 40) and several mode-specific regulations were published in 1988 and were initially based on the agency's general

Continued

MSHA has addressed the issue of alcohol and drug misuse since the 1990s. In recent years MSHA, in close collaboration with the Department of Labor's (DOL) Working Partners program,[15] has taken the lead and initiated a number of education and outreach efforts to raise awareness in the mining industry of the safety hazards stemming from the use of alcohol and drugs. MSHA and the Joseph A. Holmes Safety Association partnered and established the Professional Miner Program to recognize miners who have worked injury-free for at least three years. Miners who have been recognized as Professional Miners sign a pledge that includes a commitment to ''work to ensure a safe, healthy, and alcohol- and drug-free workplace.'' To date, approximately 24,252 miners (roughly six percent of the mining workforce) have taken this pledge.

Each of MSHA's 51 metal and nonmetal program field offices routinely holds meetings that include presentations and discussions of alcohol and drug abuse to raise awareness and provide information to mine operators. MSHA also participates in a DOL drug-free workplace alliance that provides union members and the construction and mining industries with information, guidance, and access to training resources that will help them understand the benefits of drug-free workplace programs and protect employee health and safety.

Since 2006, MSHA has encouraged mine operators and miners to participate in the National Drug-Free Work Week, which takes place in October. A number of mine operators have voluntarily implemented drug-free mine programs, and many report that these programs have improved mine safety and reduced workers' compensation costs. In addition, some of these mine operators have told MSHA that employees at their mines are supportive of these programs. However, the adoption of these programs is far from being an industry-wide practice. Many miners, particularly those working in small mines, are not likely to have access to these programs.

In December 2004, MSHA co-sponsored with the states of Kentucky, Virginia, and West Virginia, a one-day summit for individuals involved with coal mining operations and activities in the Southern Appalachian region. The summit brought together industry, labor, state and federal government officials, and public health experts to share information, expertise, and experience in dealing with the misuse of alcohol and drugs by miners. At the summit, industry representatives expressed concerns about the problems related to the use of alcohol and drugs in mines. Several coal mine operators described the effectiveness of their drug-free mine programs and expressed their concern that such programs were not universal in the industry. Also at the summit, LaJuana Wilcher, Secretary of Kentucky's Environmental and Public Protection Cabinet, announced plans to form a Mine Substance Abuse Task Force to address the increasing concern about alcohol and drug abuse in the mining industry. The Task Force, charged with gathering and evaluating pertinent information on substance abuse and its impact on the health and safety of miners, issued a Final Report in December 2005, which included recommendations for state and federal regulatory agencies as well as the mining industry on how to eliminate substance abuse among miners. Kentucky and Virginia have since adopted many of the recommendations in their new state laws that require drug-testing as part of the miner certification process.

Because of concern that misuse of alcohol and drugs compromises miner safety, in October 2005, DOL published an advance notice of proposed rulemaking (ANPRM) entitled, ''Use of or Impairment from Alcohol and Other Drugs on Mine Property,'' to inform the public that MSHA was considering a rule to address substance abuse in the mines and to gather information. Seven public information gathering meetings were also held in October and November 2005 to get additional public input.[16] Comments were sought on the following key issues: The nature, extent, and impact of the problem; what substances should be prohibited; how to address/determine impairment; whether training on workplace substance abuse should be required and, if so, what training should be required; whether/how to address substance abuse in accident investigations; what the critical/effective elements of drug-free mine programs are; and what the costs/benefits of requiring and/or implementing drug-free mine programs would be.

Although many of those commenting through oral or written statements agreed that there is a need for MSHA to take action to address substance abuse in the mines, most reports were anecdotal and data were not provided to specifically quantify the extent of the problem in the U.S. mining industry.

Since the ANPRM was published in 2005, two states have passed drug-testing laws (Kentucky in July 2006 and Virginia in April 2007) that require miners to submit to drug-testing in order to obtain and maintain their state miner's certification. A similar law was proposed in West Virginia in February 2006, but was not adopted. A subsequent version was proposed in January 2008 and is currently under consideration by the West Virginia state House Judiciary Committee.[17]

The 2006 Kentucky law requires that all applicants for mining certifications pass alcohol- and drug-tests administered by the state before a certification will be issued. Tests are conducted for eleven drugs: amphetamines, barbiturates, benzodiazepines, cocaine, marijuana, methadone, methaqualone, opiates, oxycodone, phencyclidine, and propoxyphene. The law gives the state authority to conduct post-accident alcohol- and drug-testing in the event of a serious mine accident, serious physical injury, or fatality. Although the state law does not require mining companies to do so, those that adopt a drug-free mine program, certified by the state's Office of Mine Safety and Licensing (OMSL), and include drug-testing and an employee assistance program (EAP), are eligible for a 5 percent credit on workers' compensation premiums. Mine operators are required to report miners who violate their substance abuse policy to the Kentucky OMSL. Although currently certified miners are not routinely tested by the state, the law requires annual education and training on alcohol and drug abuse for both miners and supervisors.

Training must be conducted by approved sources and may be provided on the owner's or licensee's site or at a private training site. In addition, employers are required to pay the miners when they attend and pay for the training. The year 2007 marked the

safety responsibilities rather than as a response to specific statutory authorization.

[15] The Department of Labor's Working Partners program is an education and outreach initiative that equips employers and unions with information and tools to effectively address workplace alcohol and drug problems.

[16] The public information gathering meetings were held in Salt Lake City, Utah; St. Louis, Missouri; Birmingham, Alabama; Lexington, Kentucky; Charleston, West Virginia; Pittsburgh, Pennsylvania; and Arlington, Virginia.

[17] Although there are a variety of specialty certifications that miners are required to get in order to perform certain mining functions, only a handful of states (Kentucky, Virginia, West Virginia, Pennsylvania, Oklahoma, and Colorado) require a general miner certification in order to be employed as a miner.

lowest number of mining fatalities in Kentucky history and this law is credited with causing the improvement. In the time since the law was enacted, there have been seven fatal accidents. The required toxicology reports were completed in all cases and showed evidence of recent drug use in at least one of these fatal accident cases.

According to Kentucky state officials, approximately 17,100 certified miners are actively working in Kentucky's 526 licensed mines. Since the drug-testing law was enacted, a total of 11,930 pre-certification tests have been conducted. The number of positive pre-certification tests is not known because of how Kentucky tracks the data. Since the law's inception, there have been 459 reported violations of the industry's drug-free requirement, which have affected certifications as follows: 170 certifications remain suspended, 109 are on probation, 56 have been rescinded, 89 are revoked, 22 are permanently revoked, and 13 probationary periods were completed. Employers are not required to report or record the type of drugs for which miners tested positive.

The 2007 Virginia law requires mine operators to implement a substance abuse screening policy and program for all miners. At a minimum, the programs must include a pre-employment, 11-drug urine test (the same panel that Kentucky uses). The law also requires that testing be conducted as part of an accident investigation if reasonable cause exists to suspect drug involvement or that drugs were a contributing factor to a serious accident. Mine operators are required to notify the state mining board of any failure of a pre-employment substance abuse screening test, or when a miner is discharged due to a violation of the company's substance or alcohol abuse policies (*e.g.*, a miner testing positive for intoxication while on duty status, or a miner testing positive for use of a prohibited substance without an appropriate prescription). Upon notification, any certifications held by the miner are temporarily suspended pending a hearing before the Virginia Board of Coal Mining Examiners.

According to state officials, there are 4,290 certified miners and 244 licensed mines in Virginia. To date, there have been 90 positive tests reported by companies and 3 positive tests reported as a result of an inspector-ordered test after an accident investigation. Of these, 41 have had their certificate suspended (including those waiting for their scheduled hearings), 25 certificates have been revoked, and 19 have been re-instated. Twenty-nine miners have been referred to treatment.

III. Discussion of the Proposed Rule

A. Nature, Extent, and Impact of the Problem

Employment in the mining industry during this decade has been steady at around 340,410 in about 23,054 mines (including contractors). In 2007, the Bureau of Labor Statistics reports that the industry sectors with the highest fatal occupational injury rates were agriculture, forestry, fishing and hunting (29.6 percent),[18] mining (27.8 percent),[19] and coal mining (49.5 percent).[20] It should be noted that BLS data includes oil and gas extraction, mining, and support activities for mining. While the extent of the alcohol and drug problem in mining has not been directly measured, there appears to be abuse and negative consequences in mines. Abuse of alcohol and drugs is pervasive in society and mining worksites are not immune. In fact, many communities hard-hit by drugs are those where mining is the main industry. Data collected by SAMHSA from individuals employed in the mining industry suggest that a significant number of mine operators perform pre-employment tests and perform random testing to discourage use among employed miners. Specifically, within the mining industry, nearly four out of five workers report that companies perform alcohol and drug tests on a pre-employment basis, which is nearly double the reported all-industry average. Similarly, nearly three-quarters of those working in the mine industry report random testing, which is more than double the reported all-industry average (of nearly 30 percent). These data suggest that alcohol and drug use by miners is a significant enough threat to safety to compel mine operators to voluntarily choose to conduct alcohol- and drug-testing.[21]

Since 2005, a number of media articles have highlighted drug use in the coal mines, with seven articles published since January 2007. The articles appeared mostly in local newspapers, covering situations in Virginia, Kentucky, and West Virginia.[22] An extensive front-page article discussing drugs and drug addiction in the mines of western Virginia was published in *The Washington Post* in January 2008 and republished throughout various regional papers. Several articles suggest that miners misuse drugs (mainly prescription painkillers) after becoming addicted to them during treatment for chronic work-related pain and injuries.

Some articles also mention fatalities and serious injuries in three separate mining accidents where drugs were discovered on-site or observed via post-accident drug screening, even though the investigation reports did not necessarily consider drug use to be a contributing factor to the accidents.

In the 2005 ANPRM, MSHA sought comments on the nature, extent, and impact of substance abuse in the mining workplace. The ANPRM also sought comments on the most prevalent substances used; how widely they are used in the mine; the severity of the risks associated with alcohol or drug use by mine workers; and the link between accidents or injuries and alcohol or drug use.

Many of the 65 written and oral comments received from mine operators, mining associations, and mine workers acknowledge the existence of an alcohol and drug problem that endangers mine safety. The commenters cited a number of factors regarding the prevalence of alcohol or drugs in the mining workplace. Other commenters suggested that the geographic location of mines and whether mine operators are committed to testing and alcohol- and drug-free workplaces impacts the misuse of alcohol and drugs in the mining workplace. Two commenters stated that the use of illegal drugs was most prevalent among job applicants and new hires. Another commenter stated that alcohol abuse is a problem that most often affects older workers.

A majority of the commenters agreed that the use or misuse of alcohol and drugs poses a severe or significant risk to miners' safety. FMC Corp. stated that ''miners, both surface and underground, operate expensive and dangerous equipment on a routine basis, and the use of drugs or alcohol can severely impact an individual's judgment and put co-workers and equipment at risk.'' Another commenter, Graymont Western US, Inc., noted that ''the severity of the risk imposed by a miner impaired due to alcohol or substance abuse cannot be overstated'' and ''the potential hazards associated with mining are known and well documented.'' Thus, ''permitting an impaired individual to work in an

[18] Number and Rate of Fatal Occupational Injuries, by Industry Sector, 2006—U.S. Bureau of Labor Statistics, U.S. Department of Labor.

[19] Ibid.

[20] U.S. Department of Labor, Bureau of Labor Statistics, Census of Fatal Occupational Injuries, 2006.

[21] Data are extracted from on-line tables from the SAMHSA 2002, 2003, and 2004 National Surveys on Drug Use and Health.

[22] The sources include: *The Washington Post, USA Today, The Charleston Gazette, The Courier-Journal* (Louisville, KY), *Harlan Daily Enterprise, The State Journal* (Charleston, WV), and *Coal Age Magazine.*

environment where, for example, methane gas is liberated or on or around machinery capable of causing bodily harm cannot be tolerated.'' The International Coal Group (ICG) ''believe[s] that the abuse of a controlled substance creates a very serious risk to the health and safety of all miners.'' ICG further states that ''the individual places themselves and others around them in a dangerous situation [and] [a]llowing an individual to work in an environment under the influence of a control[led] substance could affect the safe operation of machinery and the sound judgment needed to make critical decisions in performing all work task[s] in a safe manner.''

A former Nevada underground miner suggested that the work shifts, travel time to and from work, lack of sleep, and chronic pain contribute to the abuse of alcohol and drugs by miners. Another commenter specifically stated that alcohol and drug abuse exists and that ''mining companies must deal with the amount of alcohol and drug abuse, the types of illicit drugs abused, and the fact that the amount and types of prescription drugs abused varies greatly by location and time.''

The drugs of concern specifically mentioned by commenters include alcohol, marijuana, cocaine, opiates, methamphetamines, and prescription painkillers (notably methadone and oxycodone). Concern was expressed not only about the non-medical use of prescription painkillers, but also about the impact that legally used medications could have on impairment of job functioning.

The United Mine Workers of America (UMWA), on behalf of the Navajo Nation, expressed concern about a lack of substantial evidence that would directly link a particular accident to the use of peyote or natural herbs. Furthermore, the UMWA also questioned the accuracy of some of the ANPRM preamble statements and indicated that they would like to see ''data that says where the problems are, and how they exist and what we should do from there.''

Although a subsequent internal DOL review of accident reports failed to reveal a significant number of cases where alcohol or drugs were determined to be causative factors, it did reveal a lack of consistency in whether and how alcohol and drug tests are performed and in the investigative process used to determine whether alcohol or drugs may have been factors. In fact, currently accident investigations do not routinely include an inquiry into the use of alcohol or drugs and this is a failure that the proposed rule intends to address.

Although there are limited data, anecdotal reports suggest a relationship between alcohol and drug use and mine accidents. Increased concern about the issue arose in 2003 after a blasting accident at an Eastern Kentucky coal mine (Cody Mining Co. in Floyd County) in which one miner was killed and another seriously injured. Marijuana was found at the scene, and a witness reported having seen the miners snorting crushed painkillers. An autopsy of the dead miner confirmed the presence of painkillers. The surviving miner was not tested, and there was no federal or state requirement to do so. In December 2005, a 29-year-old miner (at No. 3 Mine of HandD Mining, Inc.) died after an overloaded coal hauler severed his legs. Although no discussion was included in the fatality report about whether drug use may have contributed to the accident, the hauler's driver and the dead miner both tested positive for painkillers and marijuana.

Another incident occurred at Langley Hill Quarry where a truck driver apparently fell from a parked truck onto a concrete pad, sustained facial and skull fractures and died sometime later. The report noted that ''medical records showed a blood alcohol concentration (BAC) level of 0.04 percent,'' but went on to conclude ''it could not be determined why or exactly from where [the driver] fell. There was no apparent need to have climbed onto the handrail or the rear of the truck.'' No explanation was given for why the BAC level does not specifically appear in the conclusion as a causal or contributing factor despite the fact that a 0.04 percent BAC, under the DOT regulations, is considered high enough to cause impairment and is a violation of the DOT drug rule.

At East Volunteer, a victim was operating a malfunctioning telescopic lift and was pinned between the lift platform rail and part of the ceiling infrastructure. The victim was noted in the report, under the ''human factors'' section, as having a toxicology analysis that ''revealed methamphetamine intoxication,'' but it was not mentioned in the root-cause analysis or conclusion. It is reasonable to question whether the victim's intoxication may have impacted his observation skills as the malfunction was happening and possibly slowed his decision-making on how to respond.

An alcohol- and drug-free mine program as proposed in this rule will contribute to the prevention of such incidents and provide all miners, regardless of what state they work in and the size of the mine they work for, equal safety protection from working alongside miners under the influence of alcohol and/or drugs on the job. More uniform testing and reporting would address the need to collect data about the frequency of post-accident tests that reveal alcohol or drug involvement.

B. Effective Strategies for Addressing Alcohol and Drug Problems in Mining

The ANPRM also sought data on the effectiveness of drug-free workplace programs to improve safety in the mine. Although numerous commenters expressed the belief that drug-free mine programs that include drug-testing and education were effective strategies for protecting mine safety, few compelling data were received. However, numerous mine industry employers and two state governments (Kentucky and Virginia, as discussed previously) have instituted drug-free mine programs that require drug-testing and have passed anti-drug laws specifically targeted to the mining industry and report success of these efforts.

Several commenters cited their low number of positive results on post-accident alcohol and drug tests as evidence of the effectiveness of their overall drug-free mine programs. Oxbow Mining reported that ''two relatively minor accidents occurred in which the injured tested positive for illegal drugs (THC/marijuana), [and] in both cases the injured were terminated from employment.'' Another commenter uses post-accident testing and noted that ''if we were not conducting this testing, it is reasonable to believe the problem would be much greater.''

There was a general agreement that alcohol- and drug-free mine programs are desirable. Nonetheless several commenters opined that the issue of alcohol and drugs in the mine could not be solved through additional rulemaking. More than one commenter believed there was no reason for MSHA to issue regulations either because coal companies have already adopted or implemented drug-free workplace programs or because they do not believe the problem to be pervasive. Still others expressed support for regulations that would standardize the expectation and enforcement of an alcohol- and drug-free workforce throughout the industry. The comments did include widespread support for MSHA to provide educational information and resources that would allow mine operators the flexibility to develop programs tailored to the needs of their workers and specific worksites.

C. Basis of Proposal

Mining is inherently dangerous and the misuse of alcohol and drugs increases the risk of accident, injury, or death. It is reasonable to expect that any diminution of a miner's attentiveness, concentration, dexterity, balance, or reaction time could play a contributing, if not causative, role in an accident. No one disputes that a miner who is under the influence of alcohol and/or drugs is an unacceptable safety risk. Though some mine operators have programs in place to address this hazard, the implementation of alcohol- and drug-free mine programs is far from universal. There is a need for consistency and uniformity across all types of mining environments (whether coal or metal/nonmetal, surface or underground) with regard to the regulatory prohibitions against alcohol and drugs.

The proposed rule would provide a consistent baseline for the mining industry and afford safety for all miners. Only two states currently require such programs, and even those requirements are inconsistent. Although both Virginia and Kentucky test miners for eleven drugs, only Kentucky tests for alcohol. The question could be posed as to why miners in Virginia should have to work in environments that could be less safe than those in Kentucky where more comprehensive testing programs are in place. Also, unregulated mines in states bordering those with laws could attract miners who want to avoid testing programs, thus increasing their chances of experiencing avoidable accidents and other safety hazards. Inconsistencies also exist within MSHA's current standard prohibiting the use of intoxicating beverages and narcotics in or around mines. The current standard applies only to metal and nonmetal mines, but not to coal mines. This proposal would bring consistency for alcohol- and drug-testing and treatment referral and offer the same measure of safety for all miners in all states.

The proposal is intended to prevent the safety risks that can result from the use of alcohol and drugs by those who work on mine property. Thus, under the proposed rule, possession of alcohol or drugs on mine property as well as any use of alcohol or drugs that might compromise safety while working in safety-sensitive job duties (*i.e.*, activities where a lapse of critical concentration could result in an accident, serious injury, or death) is prohibited.

Alcohol- and drug-testing is a common practice in many industries, and most private sector employers have a great deal of latitude about whether to drug test and how to do so. Several federal agencies (including the Departments of Defense and Energy, the Nuclear Regulatory Commission, and the National Aeronautics and Space Administration) have regulations that require contractors, grantees, and licensees to have fitness-for-duty requirements or drug-free workplace programs that include a variety of testing requirements, such as pre-employment, random, post-accident, and reasonable suspicion testing. The U.S. Department of Transportation (DOT) requires alcohol- and drug-testing of over 12 million workers performing designated safety-sensitive job duties in the aviation, trucking, railroad, mass transit, and pipeline industries and has codified its testing program requirements at 49 CFR part 40 (''part 40''). The Coast Guard, which began requiring alcohol- and drug-testing when it was an agency under DOT, has continued to require testing that follows DOT part 40 even though it is now under the Department of Homeland Security.

Because of the Government's interest in public safety, DOT developed and implemented alcohol- and drug-testing regulations covering the transportation industry in 1989 in the absence of specific authority to do so. Subsequently, Congress passed the Omnibus Transportation Employee Testing Act of 1991 that requires transportation industry employers who have covered employees (*i.e.*, employees in safety-sensitive positions) to have drug-free workplace programs which include both alcohol- and drug-testing. Similarly, many of the jobs in mines are safety-sensitive in that a momentary lapse of attention at a critical moment could cause significant injury not only to the individual but to many others. Thus, it is reasonable to expect that MSHA would act to ensure that, while on the job, miners are protected from alcohol and drug misuse of their colleagues. Furthermore, making alcohol- and drug-testing a standard part of an accident investigation and reporting the results would go a long way toward providing better information about the extent to which alcohol and drug use contributes to accidents in the mining industry.

The proposed rule would give needed guidelines, procedures, and training materials to mine operators who have not yet adopted or implemented a drug-free mine program. This proposal would incorporate the DOT part 40 testing procedures. While there are some variations based on identified needs within the mining industry, the proposed rule requires testing under the same circumstances as DOT (pre-employment, random, post-accident, and reasonable suspicion). Similarly, the proposed rule requires removal from the performance of safety-sensitive job duties and follows the same process of referring miners who test positive to Substance Abuse Professionals (SAP) and requiring return-to-duty and follow-up testing in order to resume performance of safety-sensitive job duties. The proposed employee and supervisor training requirements are also similar in content to the DOT rule and are intended to help the mine operator, supervisors, and miners recognize and know how to handle the signs of alcohol and drug use in the mine so that workers who are intoxicated or under the influence can be removed from the job site and sent for testing when indicated.

IV. Section-by-Section Discussion

Summary of Rule: The proposed rule would be 30 CFR subchapter N (Uniform Mine Safety Regulations) part 66 and would replace the existing metal and nonmetal standards at 30 CFR 56.20001 and 57.20001. This subchapter establishes safety regulations that apply to all mines: Coal and metal/nonmetal; surface and underground.

MSHA recognizes that the existing regulations found at 30 CFR 56.20001 and 57.20001 have shortcomings in that the existing provisions do not specify what substances are prohibited or require employers to take action when miners violate the regulations. Nor do the regulations require mine operators to train miners about the dangers that alcohol and drug use can bring into the mining environment. This proposed rule seeks to address these shortcomings and provide clear and actionable guidance for mine operators.

The proposed rule would prohibit possession of alcohol or drugs on mine property; prohibit the use of or impairment from alcohol and a specific array of drugs; require alcohol- and drug-testing of miners who perform safety-sensitive job duties and their supervisors; and require that mine operators implement alcohol- and drug-free mine programs that consist of a written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive job duties and their supervisors, and referrals to assistance for miners who violate the policy.

The proposed rule defines safety-sensitive job duties and specifies that those performing or supervising such duties would be subject to alcohol- and drug-testing under the following circumstances: Pre-Employment;

randomly at unannounced times; post-accident if the miner may have contributed to the accident; based on reasonable suspicion that a miner has used a prohibited substance; and as part of a return-to-duty process for miners who have violated the rule. At a minimum, testing would be performed for the following: Alcohol, amphetamines (including methamphetamines), barbiturates, benzodiazepines (*e.g.*, Valium, Librium, Xanax), cannabinoids (THC/marijuana), cocaine, methadone, opiates (heroin, opium, codeine, morphine), phencyclidine (PCP), propoxyphene (*e.g.*, Darvon), and synthetic and semi-synthetic opioids (hydrocodone, hydromorphine, oxymorphone, and oxycodone). Testing would also be required for any additional drugs subsequently designated by the Secretary of Labor, and nothing in the rule restricts mine operators from testing for additional drugs beyond those for which the rule requires testing.

The proposed rule would require mine operators, at a minimum, to remove those miners who violate the prohibitions from the performance of safety-sensitive job duties until the miner completes the recommended treatment and their alcohol- and drug-free status is confirmed by a return-to-duty test. Although the proposed rule requires mine operators to provide one opportunity for those violating the rule to get help and retain their job, it leaves it to the mine operator to determine the disciplinary consequences for subsequent violations. The alcohol- and drug-testing and return-to-duty procedures are specified in the proposed rule. Alcohol- and drug-testing would need to be conducted consistently with procedures incorporated by reference from DOT part 40, except in those places where specifically modified by this rule.

Effective Date and Implementing Language: The proposed rule would allow mine operators who do not have an existing alcohol- and drug-free mine program in place one year from its effective date to implement its requirements. In the event a mine operator already has an alcohol- and drug-free mine program in place that tests for at least the substances specified by the rule, the mine operator would be considered to be in compliance with the proposed rule provided the prohibitions and training requirements are consistent with those in the rule even if differing drug-testing technologies are being used. However, mine operators with pre-existing drug-free mine programs would need to come into compliance with all requirements of the rule, including drug-testing procedures and technologies, within two years of the rule's effective date. The rule would not require mine operators to conduct pre-employment testing of incumbent workers, except prior to moving a worker from a position that does not involve the performance of safety-sensitive job duties to a position that does require the performance of such duties. The proposed rule would require its training requirements for supervisors and miners to be met within 30 days of implementation of the mine's drug-free workplace program.

The decision to allow a phase-in of the new requirements is based on MSHA's desire to allow the mining industry adequate time to understand and implement the new regulatory provisions. MSHA considers one year to be an appropriate timeframe for the industry to reach compliance, given that many large mine operators already have drug-free mine and drug-testing programs in place, and that MSHA intends to provide significant compliance assistance tools, including policy templates and training materials, to the many small mine operators who do not already have such programs. The decision to consider existing programs as in compliance with the rule for a two-year period is based on the desire to minimize the regulatory burden to mine operators that already have programs deemed effective and in keeping with the purpose of this proposed rule. MSHA invites comments about the proposed amount of time allowed for implementation.

Subpart A—General

Section 66.1 Purpose

This rule is intended to protect mining's most precious resource—the miner—by preventing accidents, injuries, and fatalities at the mine associated with the misuse of alcohol and drugs. The rule would require mine operators to establish programs designed to help prevent accidents, injuries, and fatalities that could result from miners being under the influence of alcohol and/or drugs while on the job.

Section 66.2 Applicability

The mine operator would be responsible for compliance with these alcohol and drug requirements which apply to all miners performing safety-sensitive job duties and their supervisors. All coal and metal/nonmetal, surface and underground mines would be covered by the proposed rule. If the misuse of alcohol/drugs is seen as compromising safety in metal/nonmetal mines and therefore require regulation (Sections 56.20001 and 57.20001), then alcohol and drugs should be similarly regarded as having the potential to compromise safety in coal mines.

In response to the ANPRM's request for opinions on whether or not to revise the existing metal and nonmetal standard, which states that intoxicating beverages and narcotics shall not be permitted or used in or around mines and persons under the influence of alcohol or narcotics shall not be permitted on the job, there was general agreement among commenters that any revision of this standard, or any new standard, should address both the coal and metal/nonmetal sectors. In addition, the rule would apply to all mine operators, regardless of size of workforce, as a way to ensure increased protection for all miners. Commenters to the ANPRM expressed a view that it would be unfair for the rule's prohibitions to be applied selectively.

MSHA recognizes that the overall responsibility for mine safety rests with mine operators. MSHA also understands that miners play a key role in achieving mine safety and health. Thus, the alcohol- and drug-testing and training provisions would have applicability to both mine operators and those miners who perform safety-sensitive job duties and their supervisors.

Although the general prohibitions against using or possessing alcohol and/or drugs while on mine property apply to everyone working at mines, the alcohol- and drug-testing and training provisions of the proposed rule would apply only to workers assigned to perform safety-sensitive job duties and their supervisors. This limitation of coverage is intended to strike a balance between MSHA's statutory responsibility to protect the safety of miners and a desire not to propose blanket requirements applicable to miners who do not perform safety-sensitive job duties.

Another issue that MSHA considered in specifying the applicability of the rule is that of whether the rule and all of its requirements should apply to anyone performing safety-sensitive job duties, even if for a brief amount of time, or whether the rule should apply only to those who regularly or routinely perform safety-sensitive job duties. To be consistent with other safety requirements, MSHA proposes that the alcohol- and drug-testing and training requirements will apply to all those required to take comprehensive safety training under 30 CFR parts 46 and 48 (''part 46/48''), since they already take into consideration the frequency and

regularity of exposure to safety hazards in the mines. MSHA seeks comments about the determination of who performs safety-sensitive job duties and is, therefore, required to be tested and trained.

Section 66.3 Definitions

Because this proposed rule uses a number of terms that have specific meanings in the context of the implementation of alcohol- and drug-free workplace programs, this section of the proposed rule defines and clarifies the key terms used in the Uniform Mine Regulations found at 30 CFR Subchapter N, part 66.

Subpart B—Prohibitions

Section 66.100 Prohibited Substances

This section designates the substances that shall not be permitted in or around mine property and that cannot be used while performing safety-sensitive job duties, except, in the case of prescription medications, when they are used as authorized by a physician.

Consistent with the DOT rule and with all other federal drug-free workplace requirements, MSHA's proposed rule would prohibit the use, and require testing for, the following five controlled substances (commonly known as illicit drugs or the ''SAMHSA–5''):

- Amphetamines (including methamphetamines),
- Cannibinoids (marijuana/THC),
- Cocaine,
- Opiates (*e.g.*, heroin, opium, codeine, morphine), and
- Phencyclidine (PCP).

In addition, it is proposed that the unauthorized use of the following controlled substances also be prohibited:

- Barbiturates,
- Benzodiazepines (*e.g.*, Valium, Librium, Xanax),
- Methadone,
- Propoxyphene (*e.g.*, Darvon), and
- Synthetic and semi-synthetic opioids (*i.e.*, hydrocodone, hydromorphone, oxymorphone, oxycodone).

Consistent with DOT safety regulations, MSHA also proposes prohibiting being under the influence of, using, or possessing alcohol on mine property.

Because new drugs emerge that can be subject to abuse, and trends change as to what drugs are widely abused, the proposed rule includes an opportunity for additional substances to be added to the list of prohibited substances as designated by the Secretary.

Under the Controlled Substances Act it is illegal for individuals to use any of the proposed controlled substances, except when used pursuant to a valid prescription, regardless of where a person is at the time of use. Thus, the proposed rule's prohibition simply reflects existing federal law.

It is widely recognized that using illicit drugs or misusing prescription drugs can alter a person's ability to function, make decisions, and exercise the judgment necessary to ensure their safety and that of those around them when working in the mining environment. It is also widely recognized that alcohol, despite being legal, can impact a person's ability to work safely in a high-hazard environment.

The ANPRM asked for information, evidence-based or anecdotal, about which substances are used most prevalently by miners and create the most significant safety hazards at mines. A number of commenters, including mine operators and industry trade associations, specifically mentioned that the following drugs were prevalent and of concern: Alcohol, marijuana, cocaine, opiates, methamphetamines and prescription painkillers, notably methadone and oxycodone.

Commenters' concerns about prescription painkillers reflect recent data that indicate they are a growing problem. According to the 2006 National Survey on Drug Use and Health (NSDUH), prescription drug misuse was the second-ranking drug threat in terms of prevalence, with 7.0 million (2.8 percent) persons aged 12 or older using prescription-type psychotherapeutic drugs non-medically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005. Furthermore, past month non-medical use of prescription-type drugs among young adults increased from 5.4 percent in 2002 to 6.4 percent in 2006. This was primarily due to an increase in the rate of pain reliever use, which was 4.1 percent in 2002 and 4.9 percent in 2006. However, non-medical use of tranquilizers also increased over the five-year period (from 1.6 to 2.0 percent). Furthermore, data from Quest Diagnostics' *Drug Testing Index*® indicate that positive workplace drug results for amphetamines—stimulants that can include prescription drugs or diet aids—increased more than 7 percent from 2006 to 2007.

The Final Report of the Mine Substance Abuse Task Force, issued in December 2005, indicates that rates of prescription drug misuse in the Appalachian mining region may be higher than the national findings. The task force was charged with gathering and evaluating pertinent information on alcohol and drug abuse and its impact on the health and safety of miners in Virginia, West Virginia, and Kentucky and developing recommendations for state and federal agencies and the mining industry. During the group's deliberations, testimony indicated drug dependency among miners can develop from the legitimate use of prescribed painkillers. This was further supported by a Virginia Department of Health report that identified the average drug abuser in southwest Virginia as a 37-year-old male with a history of drug abuse and treatment for pain or chronic illness, with nearly one-fourth of abusers working in construction or mining jobs.

Based on its findings, the Mine Substance Abuse Task Force recommended in its Final Report a testing protocol that included illegal drugs, alcohol, and prescription drugs used illegally or in excess of therapeutic levels. Furthermore, when the International Brotherhood of Boilermakers, a union representing 65,000 workers in a variety of trades, including mining, implemented a drug-testing program for its members in 1995, it chose to test for presence of illegal drugs as well as misuse of prescription drugs. Since that time, the union reports decreased worksite accidents involving its members. A similar program operated by the International Association of Bridge, Structural, Ornamental and Reinforcing Iron Workers also tests members for prescription drug misuse.

Furthermore, the U.S. Drug Enforcement Administration (DEA) has reported that counties in eastern Kentucky lead the nation in terms of grams of narcotic pain medications distributed on a per capita basis, and that aside from marijuana cultivation and trafficking, the trafficking and misuse of prescription drugs may be the most significant current drug threat within the Appalachia High Intensity Drug Trafficking Area (HIDTA), which encompasses counties in Kentucky and West Virginia.

Commenters to the ANPRM expressed concern not only about the non-medical use of prescription painkillers, but also about the impact that even legally used prescription medications could have on functioning and whether individuals on such painkillers can safely operate mining equipment. Also, most commenters, including those representing trade associations, mine operators, and miners, specifically referenced alcohol. Although the proposed rule does not prohibit the use of prescription drugs that may have

impairing side effects, as long as they are being prescribed by a physician, MSHA is interested in further comments about experiences and concerns about the use of such substances in mining.

According to the ''Worker Substance Use and Workplace Policies and Programs'' report prepared by SAMHSA, alcohol problems are 50 percent more prevalent in the mining industry than in other industries.

The intent of the proposed rule is to improve safety in the nation's mines. MSHA proposes to prohibit misuse of alcohol and prescription drugs and use of drugs on mine property based on their known incompatibility with safe working conditions as well as observations from the industry and data indicating a high prevalence of such behavior in mining regions. At the same time, MSHA recognizes that drugs of concern may vary from location to location and change over time. It is MSHA's desire to establish a standard addressing specific drugs, but the agency also wishes to allow for flexibility should other drugs not specified in this rule threaten worker safety. MSHA seeks comments on the list of drugs that are specifically identified as prohibited substances and the means for maintaining flexibility to include additional drugs as the need arises. Public comment also is sought from individuals and entities that have experience and data regarding the specific drug compounds to be tested for within these drug groups and classes; the target parent drug and/or metabolite(s) to be tested for; the quantitated concentrations of these drugs and/or metabolites to determine an initial test presumptive positive result and a separate confirmed test result; along with the best practices and recommendations for training and certification of Medical Review Officers (MRO) in reviewing the laboratory test results for miners and differentiating use in accordance with a valid medical prescription versus illicit use.

Section 66.101 Prohibited Behaviors

This section would specify the prohibited behaviors and what is considered evidence of those behaviors, and thus a violation of the rule. Under the proposed rule the possession and use of prohibited substances on or around mine property is not permitted, unless the miner possesses a valid prescription that requires use while on mine property. In addition, reporting for or remaining on duty under the influence of or impaired by these substances would be prohibited under the proposed rule. A Blood Alcohol Concentration (BAC) level of 0.04 percent or greater would be considered verification of being under the influence of or impaired by alcohol, and a positive drug test above the cut-off levels, without a legitimate medical explanation, would constitute verification of use of a prohibited substance. MSHA proposes using the same BAC level for alcohol and cut-off levels for other substances as are used by DOT to indicate the levels at which a violation of the rule is considered to occur. However, in order to simplify the procedures and minimize confusion, MSHA has chosen not to adopt the bifurcated system used by DOT which requires temporary removal from performing safety-sensitive job duties if the BAC level on an alcohol test is between .02 and .039. MSHA believes that enforcing the 0.04 percent BAC level, which is well below what is considered under the influence by state laws governing driving under the influence, is sufficiently protective.

As MSHA's regulatory authority relates to safety, the proposed rule is intended to prevent possession and misuse of alcohol or drugs that negatively impact mine safety. It is important to note that this qualification may also relate to the use of these substances off of mine property, for example, prior to starting a work shift, since the use of prohibited substances could have extended effects that persist on the job, and therefore compromise safety. Thus, any misuse of prohibited substances that would result in effects that can compromise safety while working would constitute a violation of the rule.

The proposed rule would also prohibit miners from refusing to submit to an alcohol or drug test or attempting to alter the results of such a test. The inclusion of this provision follows the DOT model and is necessary in order to maintain the integrity of the rule's intent and its effectiveness.

Subpart C—Drug-Free Mine Program Requirement

Section 66.200 Purpose and Scope

The proposed rule would require each mine operator to implement the following five elements of an alcohol- and drug-free program: A written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive job duties and their supervisors, and referrals to assistance for miners who violate the policy. A sample model alcohol- and drug-free mine policy statement and samples of training materials are available from MSHA or the Web site at *http://www.msha.gov.*

Even absent a regulation requiring such a program, commonly called a drug-free workplace program, many mine operators have voluntarily implemented them. In fact, many, including several that responded to the ANPRM, report that these programs have improved workplace safety and reduced workers' compensation costs and non-fatal days lost. Some commenters to the ANPRM also said a perception exists among miners with alcohol and/or drug problems that absent such a program there are no real consequences of their behavior and therefore, the scope of the problem is larger at mines without programs in place. While some miners will not be dissuaded from using prohibited substances by any efforts, some commenters felt that adoption of drug-free mine programs explains why fewer positive tests are seen in their operations and why miners who have tested positive in the past choose to remain clean. Thus, MSHA believes that having programs in place at all mines would be in the best interest of all miners in order to improve safety.

The elements of a drug-free mine program that would be required by the proposed rule reflect the well-established ''five-step'' model the federal government has used for its own drug-free workplace program since the 1980s and encourages private sector organizations to adopt through advisory programs run by both the U.S. Department of Labor and the U.S. Department of Health and Human Services/Substance Abuse and Mental Health Services Administration. Many of the mine operators responding to the ANPRM described the adoption of these elements.

Section 66.201 Written Policy

A written policy forms the foundation for a drug-free mine program. The proposed rule would require each mine operator to develop a written policy and provide it to all miners covered by the rule. Each mine's policy could be tailored; however, each one would, at a minimum, address the purpose of the rule and policy; contain a clear description of the prohibited behaviors under the rule; outline the means, including testing, for determining if the policy has been violated; include an explanation of the consequences for violating the policy; and requirements for training. It was generally agreed upon by ANPRM commenters that a policy is the most logical vehicle for clearly communicating to miners what is expected of them. Written policies are standard practice for safety policies in mining as well as other industries.

Furthermore, MSHA intends to assist mine operators in developing their policy by providing a sample template that can be used to address all required elements that can be tailored to include optional elements at the mine operator's discretion. A mine operator must ensure that every miner has been informed of the policy. The proposed rule requires that a mine operator must provide a copy of the written policy to the miners' representative or post the policy on a bulletin board in a common area in the event that the miners' do not have a representative. Mine operators may also choose to distribute the policy during the alcohol and drug-free awareness training sessions or distribute the policy in an electronic format; however, these additional means of distribution are not required. The rule would require that the policy be reviewed during training sessions and made available upon request. MSHA invites comments on how the policy should be provided to miners.

Section 66.202 Education and Awareness Program for Nonsupervisory Miners

Under this section of the proposed rule each mine operator would be required to implement an education and awareness program for nonsupervisory miners to provide them with the information they need to fully understand and comply with the rule. Those miners currently required to take comprehensive safety training under parts 46 and 48 would be required to take the training required by the proposed rule. The proposed required amount of time for this training would be 60 minutes for new hires and 30 minutes annually for all nonsupervisory miners. Topics addressed would include a review of the policy requirements; generalized information about the nature of alcoholism and drug addiction; its impact on work performance, health, and personal life; and types of help available for individuals with alcohol and/or drug problems.

Many commenters to the ANPRM support this type of training for miners. One commenter from the workplace drug prevention field stressed the importance of educating miners so that they fully understand the safety issues regarding alcohol and drug abuse rather than simply preaching about how bad alcohol and drugs can be. Another commenter, a safety director for a coal company, felt that education was important to encourage those with alcohol or drug problems to seek help, but cautioned against modifying MSHA's existing training requirements. By contrast, a number of other commenters from within the mining industry specifically suggested such training should be incorporated into MSHA's existing training.

Although concerned about the number of required topics that already must be covered under parts 46 and 48, MSHA believes that it is appropriate to include education on alcohol and drug awareness in the required safety training both for new miners and as part of the annual refresher training. However, the proposed rule would require that the time allotted to this training be added to the total number of hours required under parts 46 and 48 so that there is sufficient time to cover all necessary training topics. The ANPRM did not specifically ask the public to comment on how much time should be dedicated to new miner and annual refresher training on alcohol and drugs, or the specific training media or methods that would be most suitable, and few commenters volunteered such information in their comments. MSHA is proposing to follow the standard established by the state of Kentucky, which requires 60 minutes of initial substance abuse training for new miners. This is also consistent with the Federal Transit Administration (FTA) requirement of 60 minutes of initial training on the alcohol- and drug-testing rule. In addition, MSHA is proposing 30 minutes annually thereafter for nonsupervisory miners to review the requirements and to remind miners of help that is available. MSHA believes this is appropriate given the need to regularly remind miners of the necessity of following any other safety practice. Furthermore, it is believed that doing so annually may encourage those with problems to seek help before they violate policy or create safety hazards. MSHA invites comments about the amount of employee education that is needed.

The proposal would require that the training be delivered by a competent person knowledgeable about workplace substance abuse, this rule's requirements, and the mine operator's policy. MSHA has already developed a number of materials that can be used to fulfill this employee education requirement. However, the training may be delivered using various technology or methods. Videos or other audio-visual materials may be used to supplement interactive training but cannot be used as a sole means of training.

MSHA invites comments about the amount and type of training for nonsupervisory miners and about the methods appropriate for delivering this training and also about the best means for assuring that training is delivered by qualified personnel.

Section 66.203 Training Program for Supervisors

Under this section of the proposed rule each operator would be required to implement a training program for supervisors to make them aware of their responsibilities in ensuring compliance with the rule; recognize and deal with miners who have performance problems that may be related to alcohol and/or drugs; understand how to refer miners to available assistance; and know how to make determinations for requiring a reasonable suspicion or post-accident test.

The majority of commenters to the ANPRM support this type of training. Of particular note was concern that if supervisors are responsible for making referrals for alcohol- and/or drug-testing based on reasonable suspicion, they must be adequately trained on how to make that determination. Several mine operators who commented said they already have a training program for supervisors and provided information about their programs.

MSHA is proposing that a minimum of two hours of initial training be provided to each supervisor with an additional one hour of training annually thereafter. The proposal would require that the training be delivered by a competent person knowledgeable about workplace substance abuse, this rule's requirements, and the mine operator's policy. MSHA has already developed a number of materials that can be used to fulfill this employee education requirement. However, the training may be delivered using various technology or methods. Videos or other audio-visual materials may be used to supplement interactive training but cannot be used as a sole means of training.

MSHA invites comments about the amount and type of training for supervisors and about the methods appropriate for delivering this training and also about the best means for assuring that training is delivered by qualified personnel.

Although all those who are in a position to observe and direct the work activities of others may have opportunities to discover reasons to suspect a miner is misusing substances, and hence benefit from reasonable suspicion training, it may not be wise to spread the authority to initiate such tests too broadly. MSHA proposes to leave it to the mine operators to determine who must receive this training. MSHA seeks comments on this proposal.

Section 66.204 Miner Assistance Following Admission of Use of Prohibited Substances

This section of the rule discusses actions that must be taken by mine operators following the admission of use of prohibited substances by miners. Mine operators are required to make such miners aware of available assistance through an employee or miner assistance program, a Substance Abuse Professional (SAP), and/or other qualified community-based resources.

MSHA recognizes the desire of mine operators to retain skilled miners who address and subsequently recover from their alcohol and/or drug problems. Information received in response to the ANPRM and anecdotally from the 2004 Summit and other sources suggests that mine operators may be able to return certain miners to work without compromising safety if they have taken advantage of access to appropriate treatment, continuing care, and supportive services. Several mine operators with existing Employee Assistance Programs (EAP) reported an approximately 50 percent success rate.

It is MSHA's intention to encourage miners to voluntarily seek assistance, but not to allow them to do so to avoid testing or other requirements under the proposed rule. MSHA invites comments on this provision. Because MSHA believes that alcohol and drug use is a serious safety problem and that addiction is a treatable disease, recognizes that mine operators need to retain experienced miners, and understands the critical roles mines play in the vitality of their local economies, MSHA seeks comments about the extent to which third party health benefits are available to cover the cost of SAP and treatment services for miners covered by the rule. MSHA also seeks comments on all aspects of the miner assistance provisions required by this rule.

Subpart D—Alcohol- and Drug-Testing Requirements

Section 66.300 Purpose and Scope

Although the ANPRM did not specifically ask for comments about the advisability of alcohol- and drug-testing, it did ask for comments about how impairment from prohibited substances should be determined. Drug-testing was the majority response, although some commenters noted that drug-testing in and of itself does not determine impairment, most commenters agreed that testing can be an effective deterrent to being impaired on the job, which ultimately is the positive effect desired.

Based on ANPRM comments received, as well as anecdotal information from the 2004 Summit, MSHA believes that alcohol- and drug-testing is an effective deterrent to impairment on the job, and therefore section 66.303 of the proposed rule would require mine operators to conduct alcohol- and drug-testing in certain specified circumstances. Similar drug-testing rules for miners were recently adopted by the states of Virginia and Kentucky. Furthermore, drug-testing is a safety practice widely used by many private-sector operators, particularly those in industries considered high hazard, and data indicate its positive effects. Notably, a study of the construction industry workplaces that conduct drug-testing revealed that they experienced a 51 percent reduction in injury rates (from 8.92 incidents per 200,000 down to 4.36 incidents per 200,000) within two years of implementation, compared with a 14 percent average decline in injury rates among construction companies in general.[23]

Although there is widespread recognition among commenters about the merits of alcohol- and drug-testing, there were many concerns expressed about the various types of alcohol- and drug-testing and the exact procedures to be used. These specific concerns are discussed in the preamble relative to each type of testing that MSHA is proposing. Some ANPRM comments, including those from union representatives and trade associations, opposed any regulatory requirement for mine operators to conduct alcohol- and drug-testing. For example, a representative from the UMWA expressed skepticism that an alcohol- and drug-testing rule was necessary, citing the lack of data showing that alcohol or drugs significantly contribute to mining accidents and opines that such a rule would be unenforceable. Although he did not expressly state an opposition to alcohol- and drug-testing, he did suggest that to be effective, MSHA should do the testing itself rather than relying on the mine operators to do so. Many commenters representing mine operators expressed confidence in existing company alcohol- and drug-testing programs and felt there was no need for MSHA to impose a burdensome requirement in this area.

MSHA proposes to incorporate the DOT part 40 alcohol- and drug-testing procedures. Mine operators should read ''MSHA'' where these procedures refer to ''DOT.'' Consistent with DOT part 40, MSHA is offering mine operators the option to use service agents to perform the functions required by this subpart including services for collection of urine specimens, a certified Breath Alcohol Technician (BAT), a laboratory, Medical Review Officer (MRO), and a Substance Abuse Professional (SAP). The proposed rule includes definitions for the various types of service agents. However, MSHA, unlike DOT part 40, proposes testing for ten substances rather than five.

The proposed rule's requirements prescribe breath testing for alcohol and urine collection procedures for drug-testing; however, it is MSHA's intent to follow the U.S. Department of Health and Human Services' (HHS) lead should alternative testing procedures be approved for federal programs. MSHA is aware that some mine operators are already testing using alternative methods such as point of collection devices and alternative specimens and seeks comments and information on what their experience has been. This information will help MSHA determine whether existing mine operator programs differ significantly from proposed requirements.

The proposed rule contains a requirement that mine operators use only HHS-certified laboratories to test collected samples. HHS-certified laboratories must comply with the applicable provisions of HHS' Mandatory Guidelines for Federal Workplace Drug Testing Programs concerning accessioning and processing urine specimens. These provisions require laboratories to conduct validity testing to determine whether certain adulterants or foreign substances have been added to the specimen to mask or destroy the drug or drug metabolite that the specimen may contain as well as determine if the specimen was diluted. However, since HHS currently only certifies laboratories to test for the five illicit drugs for which federal agencies test, MSHA also proposes to require that laboratories that conduct testing under this rule be certified by the College of American Pathology (CAP) to perform Forensic Urine Drug Testing for the additional substances specified by this rule.

Although MSHA proposes to adopt DOT part 40 requirements, it does not propose to monitor or review the performance of service agents, including laboratories, used by mine operators to comply with the rule's requirements. Rather, MSHA intends for mine operators to contract with service agents who deliver quality services, possess appropriate certifications, and follow

[23] Minchin, Jr., R.E., Glagola, C.R., Guo, K. and Languell, J.L. ''Case for Drug Testing of Construction Workers,'' Journal of Management in Engineering 22.1 (January 2006): 43–50.

part 40 requirements for the collection, processing, and analysis of specimens and the reporting of results. By relying on experienced and qualified service agents who adhere to and are being monitored by existing HHS and DOT standards, MSHA believes that the accuracy, validity, reliability, and integrity of the testing process will be maintained.

Section 66.301 Substances Subject to Mandatory Testing, and Section 66.302 Additional Testing

These sections identify the substances for which testing would be required. They are alcohol and ten drugs: amphetamines (including methamphetamines), barbiturates, benzodiazepines (*e.g.*, Valium, Librium, Xanax), cannabinoids (marijuana/THC), cocaine, methadone, opiates (*e.g.*, heroin, opium, codeine, morphine), phencyclidine (PCP), propoxyphene (*e.g.*, Darvon), and synthetic and semi-synthetic opioids (hydrocodone, hydromorphone, oxymorphone, and oxycodone). This ''ten-panel'' drug test is commonly used and both Virginia and Kentucky state laws already require testing of miners for these drugs. The decision to include these drugs is based in part on indications from commenters to the ANPRM who have extensive experience in the alcohol- and drug-testing field. Commenters in the mine industry also highlighted the need to address alcohol and prescription drug abuse. Findings from federal drug-use surveys and 2008 data from the Quest *Drug Testing Index*® show that prescription drug-abuse is rising in the workforce, substantiating other ANPRM comments. It is worth noting that many private industry employers, including numerous mine operators, already test for these drugs. As previously indicated, HHS/SAMHSA has already established workplace drug-testing cut-off values for amphetamines, cannabinoids, cocaine, opiates, and phencyclidine, which are commonly referred to as the ''SAMHSA–5.'' At present, there are no federal workplace drug-testing standards for barbiturates, benzodiazepines, propoxyphene, methadone, or synthetic/semi-synthetic opioids, all of which can be legally prescribed.

Testing for abuse of prescription drugs is complicated, in that determinations of abuse can only be made after ascertaining: (1) Whether the individual being tested has a legitimate prescription; and (2) if a legitimate prescription exists, whether the individual is using the medication in accordance with the prescriber's instructions. In many instances, this is a case-by-case determination that can only be made by examining the half-life [24] of the medication; the prescribed dosage; and the individual's metabolic rate, and comparing this information to the amount of medication in an individual's system at the time of testing. Any deviations from the expected levels may indicate possible abuse. Various laboratories and industries have developed testing cut-off levels based on the concentration levels at which these substances can be detected via urine testing. Although each case will require individual analysis, MSHA has proposed cut-off levels based on the range of levels being used by major laboratories and industries currently testing for these substances. The tables below show commonly used cut-off levels for these substances.

Screening

	DOL (proposed) (ng/ml)	Quest Diagnostics (ng/ml)	European workplace standards (ng/ml) [25]
Screening			
Barbiturates	300	300	200
Benzodiazepines	300	300	200
Propoxyphene	300	300	300
Methadone	300	300	300
Synthetic and Semi-synthetic Opioids	300	(*)	n/a
Confirmation			
Barbiturates	200	200	150
Benzodiazepines	200	200	100
Propoxyphene	200	200	300
Methadone	200	200	300
Synthetic and Semi-synthetic Opioids	300	(*)	n/a

* Varies.

Data on cut-off levels for other synthetic and semi-synthetic opioids were less readily available. Six laboratories offering urine testing for oxycodone can detect levels of 100 ng/ml of this substance in subjects' urine.

This list of prohibited substances could be revised in the future at the Secretary's discretion and as changes in drug-abuse trends occur. Nothing in the rule prohibits mine operators from testing for additional drugs under their own authority. Though it is advisable that any additional drugs be referenced in the mine operators' drug-free workplace policy statements and that testing be conducted consistent with established professional standards, the rule does not speak to such matters. It is allowable for mine operators who choose to test for additional drugs to use the same sample to do so. However, though the mine operator may choose to treat positive tests for the additional drugs the same way as for those tested under this rule, it is not required. In other words, it is not considered a violation of this part for a miner to use drugs not specified in the rule though it may violate other laws. Comments received during the ANPRM process noted that there may be times when drugs abused by miners may not be among those specified in a rule. By not restricting mine operators from testing for the use of additional drugs, the rule would enable mine operators to tailor their drug-testing policy and program as appropriate for their communities and to adapt it as needed based on changing trends in drug use. It also reflects standard latitude given to most private

[24] This is the period of time required for the concentration or amount of drug in the body to be reduced by one-half.

[25] Caplan, Y.H. & Huestis, M.A. (Eds.) (2007). Workplace Testing. In S. Karch (Ed.) *Drug Abuse Handbook, 2nd Edition.* Boca Raton: Taylor & Francis Group, LLC.

sector companies. MSHA invites comments about the required panel of drugs subject to mandatory testing.

Section 66.303 Circumstances Under Which Testing Will Be Required

The proposed rule would follow the DOT part 40 testing guidelines and require testing in the following circumstances: Pre-employment testing, random testing, post-accident testing, reasonable suspicion testing, and as part of a return-to-duty and follow-up process for miners found to be in violation of the alcohol and drug prohibitions.

MSHA invites comments about the circumstances under which testing is warranted, and should therefore, be required.

Section 66.304 Pre-employment Testing

The proposed rule would require mine operators to ensure that each miner take a pre-employment alcohol- and drug-test and produce a negative result before performing safety-sensitive job duties. Pre-employment testing includes testing new applicants for safety-sensitive positions as well as incumbent miners if they are switching from positions that do not involve safety-sensitive job duties to positions that involve safety-sensitive job duties. The purpose of pre-employment testing is to prevent hiring those who are unable to abstain long enough to be able to pass such a test, and to discourage those who actively use drugs from applying. Because pre-employment testing for alcohol cannot be conducted pursuant to the Americans with Disabilities Act (ADA) until after a conditional offer of employment has been made, the proposed rule would require that mine operators conduct alcohol tests only after such an offer has been made, but before a miner performs safety-sensitive job duties. Since the ADA does not impose similar restrictions on drug-testing, mine operators can conduct those tests at any time in the application and hiring process and do not need to wait until a conditional offer of employment has been made.

Pre-employment testing is widely used in the private sector and several mine operators responding to the ANPRM reported that they already conduct such testing. Although some commenters expressed concerns that pre-employment alcohol- and drug-testing would make it difficult for them to hire experienced miners due to labor shortages in some areas, others remarked that pre-employment testing alone is not sufficient to keep drug users out of the mine since even habitual drug users can usually abstain long enough to produce the required negative result. Most agreed, however, that pre-employment testing is a necessary element of an effective alcohol- and drug-free mine program. MSHA agrees that pre-employment alcohol- and drug-testing sends a clear message that misuse of alcohol and drugs will not be tolerated and discourages many with alcohol and/or drug problems from applying, and therefore proposes to require such testing as part of the proposed rule. Under the proposal, an applicant could not be hired if their alcohol test result is a BAC of 0.04 percent or above.

Although mine operators may choose to require that all miners who will be performing safety-sensitive job duties and their supervisors submit to alcohol- and drug-tests when the program is initiated, the rule will not require that incumbent workers take pre-employment tests to continue performing their safety-sensitive job duties. MSHA invites comments about the proposed pre-employment alcohol- and drug-testing provisions.

Section 66.305 Random Testing

For the purposes of this rule, random testing is unannounced testing performed on miners who perform safety-sensitive job duties and their supervisors, whose unique identifying information (*e.g.*, an employee number) has been placed in a testing pool from which a scientifically arbitrary selection is made. The purpose of random testing is to deter current miners from using drugs illegally or coming to work impaired by alcohol or drugs. Many commenters expressed support for adopting random testing because of its strong deterrent effect and also shared that many of their existing programs require random testing at various annual rates. Although some commenters expressed skepticism about whether random testing is always truly random, and expressed fear that it can be used to target specific individuals, most confirmed that when done according to correct procedures, it can be an effective way to deter use provided that everyone is equally subject to such testing. Some expressed belief that it is, in fact, a more objective method of determining who gets tested than relying on supervisors to recommend drug tests based on reasonable suspicion, which, even with adequate training, is a subjective judgment.

In order to get an indication of random alcohol- and drug-testing rates used by mining industry operators, we reviewed the policies shared during the 2004 Summit, comments made during the 2005 ANPRM public meetings, and written submissions received in response to the ANPRM. Thirteen stakeholders were identified with random alcohol- and/or drug-testing programs, and 11 of these volunteered the percentages used. There was a wide variation in rates used, ranging from 1 percent to 100 percent. Most companies who shared this information were testing in the range of 10 percent to 30 percent annually.

After considering the broad spectrum of experiences with random testing, including those of DOT and the federal agency programs, MSHA is proposing to include it as a required element of the alcohol- and drug-testing rule and proposes to require that a minimum of 10 percent of miners that perform safety-sensitive job duties and their supervisors be randomly tested each year. The rule proposes to allow mine operators discretion to test at higher rates, and MSHA proposes to leave to the mine operator's discretion the frequency at which random testing is done so long as the floor of 10 percent is reached each calendar year. The rule would require that random testing be done on an unannounced, unpredictable schedule. Miners who are on leave or otherwise absent from the workplace would be tested at the next available opportunity (*e.g.*, immediately upon their return to work).

MSHA recognizes that small mine operators may not have a pool of miners large enough to set up a meaningful random selection pool and so we would allow mine operators to fulfill the random testing requirement by forming or joining consortia for that purpose.

MSHA invites comments about the floor rate at which testing would be conducted and what options, including joining consortia, are viable for small mine operators to fulfill the random testing requirement of the proposal.

Section 66.306 Post-accident Testing

The proposed rule would require that post-accident tests be conducted by mine operators whenever an accident or occupational injury must be reported to MSHA. MSHA proposes that for fatalities and non-fatalities all surviving miners involved in any work activity that could have contributed to the accident or occupational injury be tested for alcohol and drug use as soon as practical, but no later than eight hours after the incident for alcohol and 32 hours for drugs. The differing testing windows are proposed because alcohol clears the system much more quickly than drugs. An alcohol-test result obtained beyond the eight-hour window

would not tell an investigator anything about whether the miner was under the influence at the time of the incident. The proposed rule leaves the decision about who must be tested to the mine operators, but proposes a broad reach such that anyone who could possibly have contributed to the accident could be tested. It is the intent of the proposal that mine operators make the decision to test as quickly and objectively as possible, because delay in conducting tests makes the results irrelevant to the accident investigation. Because it would be useful to collect information about whether the victim in a fatality had used alcohol or drugs in order to determine the cause and to prevent future accidents, MSHA is proposing to require post-mortem toxicology testing of the deceased. Although some states require approval of the next of kin in order to conduct and release autopsy results, a toxicology test is not nearly as invasive as an autopsy. Therefore, MSHA believes its authority to investigate following fatalities extends to requiring the performance of toxicology tests, for at least the same substances for which others are tested following an accident.

Although the proposed rule requires mine operators to make the decisions about when and whom to test following a reportable accident, MSHA proposes to give its investigators authority to require such tests if they arrive within the testing window (eight hours for alcohol and 32 hours for drugs) and determine that additional miners not already tested by the operator may have contributed to the accident. All post-accident tests would be performed at the mine operator's expense. The proposed rule also would require that post-accident tests would not be allowed to delay the delivery of necessary medical attention to injured miners. MSHA invites comments on the proposed post-accident testing provisions.

Testing following an accident can help determine whether alcohol and/or drugs were a factor in the accident. It is important to note that although the result of post-accident testing may determine recent drug or alcohol use, it cannot in and of itself prove that impairment from those substances caused the accident. The ANPRM specifically asked for comments about whether alcohol and drug inquiries should be added to post-accident investigations and, if so, what types of inquiries should be made. Several commenters supported post-accident alcohol- and drug-testing as part of these investigations. MSHA has not proposed specific changes to the accident investigation process (see 30 CFR 50.11), but welcomes comments on how the alcohol- and drug-testing results should be documented in accident reports as well as how they should be evaluated during an accident investigation to help determine the cause of the accident. MSHA also welcomes comments from those that already perform post-accident tests regarding the number of cases where alcohol or drugs were determined to be a contributing or root cause of the accident, and the frequency of all accidents/injuries where tests reveal some alcohol or drug involvement.

Section 66.307 Reasonable Suspicion Testing

Reasonable suspicion testing is conducted when a supervisor documents observable signs and symptoms that lead him or her to suspect alcohol or drug use. Such testing is a tool that supervisors can use to confirm or rule out alcohol or drugs as the cause of performance problems and behaviors that in and of themselves could create hazards. Under the proposed rule, if a test is positive the miner can, at least upon the first such violation, be referred to evaluation and treatment in order to get the help needed to be able to return to safe and productive work.

A number of those speaking at ANPRM public meetings discussed the pros and cons of reasonable suspicion testing. Most agreed that it was a useful tool available to management to verify suspected alcohol or drug use. However, several expressed their reservations about whether supervisors, even with considerable training, can readily identify when someone is impaired by drugs, noting that alcohol is much easier to detect since there is generally an odor one can smell. Others stated that there is so much subjective judgment required to make a reasonable suspicion determination that such testing is problematic to implement—especially within a regulatory framework. Some noted that even when reasonable suspicion testing is required, as it is under the DOT regulations, supervisors often fail to utilize this option. Many commenters to the ANPRM underscored the importance of providing adequate training to supervisors on how to make such determinations.

MSHA believes reasonable suspicion testing is necessary to allow individual mines to respond quickly and appropriately to individual situations. Thus, the proposed rule would require mine operators to include reasonable suspicion testing in their alcohol- and drug-free mine program. It specifies that mine operators' determinations to conduct reasonable suspicion tests must be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the miners and that only those trained in making these determinations could do so. The proposed rule leaves it to the mine operator's discretion to determine who should be trained and authorized as a supervisor to make these determinations.

Subpart E—Operator Responsibilities, Actions, and Consequences

Under the proposed rule, mine operators would generally be cited for failure to comply with the requirements to institute an alcohol- and drug-free mine policy and program. Several of those commenting on the ANPRM expressed concern about whether mine operators should be held accountable for the actions of miners who violate the policy prohibiting use of alcohol or drugs while performing safety-sensitive job duties. It is not MSHA's intent to sanction mine operators who implement an alcohol- and drug-free mine program that includes alcohol- and drug-testing as prescribed in part 66, and who demonstrate a good faith effort to enforce their policy. However, mine operators who fail to implement and enforce these policies would be cited, specifically in cases where failure to enforce the provisions of the rule by monitoring miner compliance results in fatalities, accidents or injuries. MSHA invites comments as to the appropriate means for enforcing the provisions of this proposed rule.

Section 66.400 Consequences to Miner for Failing an Alcohol or Drug Test or Refusal To Test

Several commenters said that an alcohol and drug regulation should hold individual miners accountable for their actions rather than place responsibility solely on mine operators, and several of these commenters referenced the smoking materials prohibition as a precedent for doing so. A number of ANPRM commenters, including the National Mining Association (NMA) and the National Stone Sand and Gravel Association (NSSGA), specifically suggested that some form of monetary penalty, like the fines for smoking, should be levied on miners who violate prohibitions against using or being under the influence of alcohol and drugs at the mine.

This proposed rule would not impose a monetary penalty on miners possessing, using or being under the influence of alcohol or drugs while at work. Rather, the proposed rule would require that miners who violate the alcohol and drug prohibitions be

immediately removed from performing safety-sensitive job duties and not allowed to perform such duties until their alcohol- and drug-free status is assured, as specified in section 66.406. The process for removal, referral and potential return to work has been modeled on the provisions of the DOT rule.

Section 66.401 Operator Actions Pending Receipt of Test Results

This section of the proposed rule specifies what actions mine operators would be required to take while awaiting the results of alcohol or drug tests. For those miners who are sent for testing based on random selection, mine operators would be required to allow miners to immediately return to performance of duties. However, in those cases where a miner is sent for testing either because the mine operator has determined that there is reason to suspect that the miner has been misusing prohibited substances or that he/she may have contributed to the cause of an accident, the mine operator would be required to remove the miner from performing safety-sensitive job duties until the test results are received. Doing so protects other miners from potential hazards when there is a reason to suspect that the miner being tested has been misusing prohibited substances. It is left to the mine operators' discretion whether or not the miner can perform other non-safety-sensitive job duties in the interim. The proposed rule would require that miners suspended from performing safety-sensitive job duties pending results all be treated in the same manner with respect to this policy and that no action adversely affecting the miner's pay and benefits pending the completion of the process would be taken. Whether or not the miner is paid during the suspension if the ultimate verified test result is positive, is left to the mine operator's discretion subject to labor-management agreements. MSHA believes that removing those who are tested for a reasonable suspicion or after involvement in an accident while awaiting the results is necessary to protect the safety of all miners.

Section 66.402 Substantiating Legitimate Use of Otherwise Prohibited Substances

This proposed section states that it is up to the mine operator to make sure that miners have ample opportunity to demonstrate that any use of prohibited substances (as defined in this rule) has been authorized by a physician. It further specifies that the possession of a valid prescription alone is not sufficient proof of legitimate use. This provision allows the miner an opportunity to provide evidence that the prohibited substance(s) has been legitimately prescribed and allows the MRO to conduct a medical interview of each miner following a confirmed positive test; review the miner's medical history; and consider not only the possession of a valid prescription, but any other relevant biomedical factors presented by the miner. The MRO may also direct miners to undergo further medical evaluation and/or contact the miner's physician or other relevant personnel for further information. It is not the intent of this provision to have the MRO determine whether the use of a given substance is compatible with the performance of safety-sensitive job duties, as this is a determination that is best made by the miner's physician.

MSHA has modeled this provision on the DOT MRO review process and invites comments on the application of this process within the mining industry, specifically for those instances in which positive test results are received for prescription drug use that is legitimate and appropriate, but for which the MRO believes there may be safety concerns based on the nature of the medication. MSHA is also interested in learning from mine operators who already test for these additional substances about their experience differentiating legitimate from unauthorized use and for dealing with discovery of use of substances that, even when used as authorized, may have impairing effects incompatible with performance of safety-sensitive job duties.

Section 66.403 Operator Actions After Receiving Verified Test Results

This section specifies the actions mine operators must take upon receiving a verified alcohol- or drug-test result. For alcohol tests with a resulting BAC of 0.04 percent or higher or drug test results that are verified by the MRO as positive, adulterated or substituted, the mine operator must immediately remove the miner from performance of safety-sensitive job duties and refer him or her to an SAP without waiting for the subsequent results of any split specimen testing. However, the mine operator is not required to provide referral assistance upon any subsequent offenses.

MSHA invites comments about the provisions on what action mine operators must take upon receiving alcohol- and drug-test results.

Section 66.404 Evaluation and Referral

This section specifies that in each case of an alcohol- and drug-free mine policy violation the miner would be provided with a listing of SAPs. However, the proposed rule would only require mine operators to offer job security to those miners who violate the alcohol- and drug-free mine policy for the first time provided they follow the SAP treatment recommendations and required return-to-duty procedures. For subsequent offenses, mine operators would have the discretion to specify disciplinary consequences, up to and including termination. Although MSHA believes it may be in the mine operator's interest to pay for SAP and treatment services in order to retain experienced miners, it is left up to the mine operator's discretion and collective bargaining agreements whether or not to do so.

Many mine operators who responded to the ANPRM said they find offering assistance to those with alcohol and drug problems, most commonly through an Employee Assistance Program (EAP), a successful avenue for returning miners to work and assisting mine operators in retaining valued employees. In addition, one commenter expressed the opinion that rehabilitated miners are often an improvement to safety and a positive model to others. Several responders also commented on the value of an established avenue for employee assistance in emergency situations involving alcohol and drugs. Given this, the proposed rule prescribes a process through which miners who violate their employer's alcohol- and drug-free mine policy would, on first offense, be referred for assessment by a Substance Abuse Professional (SAP) and referred for treatment as appropriate, and following this, be offered the opportunity to return to duty provided compliance with certain requirements.

However, it is important to note that EAP programs include a range of services that go beyond those required to achieve recovery from alcohol and drug problems, and consequently MSHA believes that a more targeted approach is best for addressing the alcohol and drug issues outlined in the proposed rule. Therefore, MSHA only requires that mine operators make SAP services available rather than comprehensive EAPs. The proposed rule also allows the mine operator to make these services available to miners who have not violated the policy, as well as to those who have violated it more than once, as determined by the mine operator's policy.

It is also important to note that although EAPs can perform SAP functions, the drug testing and compliance monitoring function of SAPs (as specified in this proposed rule), falls outside the scope of a typical EAP practice. Therefore, simply having an EAP would not necessarily meet this requirement unless the EAP agrees to perform the SAP monitoring functions. We invite comments on the inclusion of SAP functions without EAPs.

Section 66.405 Return-to-Duty Process

The proposed rule also specifies that prior to returning to performing safety-sensitive job duties, miners must follow the treatment recommendations of the SAP, be re-evaluated by the SAP, and comply with the testing requirements established by the SAP. Miners and operators must abide by the recommendations of the agreed upon qualified SAP and may not seek a second opinion from another SAP following the initial evaluation. Although the SAP verifies compliance with the recommended treatment, it is the mine operator who decides whether the miner will return to work performing safety-sensitive job duties. However, the proposed rule specifies that a miner who has successfully completed the recommended treatment and passed the return-to-duty tests may not be discharged for his/her first offense.

Several mine operators shared that their current policies include similar provisions. MSHA believes the proposed rule incorporates appropriate accountability but invites comments about the consequences that would be imposed upon miners by the proposed rule. MSHA also invites comments about the evaluation and referral process and the role of the SAP in recommending treatment and determining compliance.

Section 66.406 Return-to-Duty Testing and Follow-Up Testing

Return-to-duty testing is a one-time announced test that is required when a miner who tested positive in the past has completed required treatment and is ready to return to a position that involves performing safety-sensitive job duties. Follow-up testing is conducted periodically after a miner returns to work after completing treatment. It is administered on an unannounced, unpredictable basis for a pre-specified period of time. A number of commenters remarked on the importance of return-to-duty and follow-up testing to monitor compliance and provide assurances that those who have previously violated the alcohol- and drug-free mine policy do not return to using prohibited substances.

MSHA's proposed rule includes return-to-duty and follow-up testing as a protection for mine operators and miners. MSHA proposes adopting this process as a way for mine operators to allow qualified, skilled miners to return to jobs where they are needed, while also providing protections to ensure they are safe to do so.

Specifically, the proposed rule would require miners to have a verified negative return-to-duty drug-test and an alcohol-test reading of less than a BAC of 0.04 percent before returning to the performance of safety-sensitive job duties. The number and frequency of follow-up tests would be solely determined by the SAP with a minimum of six unannounced tests in the first 12 months following return to work and continuing for a maximum of 24 months. MSHA invites comments about the provisions for return-to-duty and follow-up testing.

Subpart F—Recordkeeping and Reporting

Section 66.500 Recordkeeping Requirements

The proposed rule specifies that records of alcohol- and drug-tests would be protected as confidential communication between the mine operator and the miner. The proposed rule also prohibits sharing such records with others and requires secure storage so that they cannot be accessed by unauthorized individuals. MSHA believes this provision is necessary to ensure the privacy of individuals.

MSHA, the mining industry, and individual mine operators can all benefit from establishing an accurate quantifiable baseline of alcohol and drug problems, and tracking the trends over time that result from the proposed rule. Consequently, the proposed rule would require mine operators to keep records on the number of miners in safety-sensitive job positions that are covered by the rule and results from the various types of tests performed. An alcohol- and drug-free mine program would be required to be made available upon request. Under the proposal, MSHA would be able to analyze the information, which could add to an understanding of the extent of alcohol and drug abuse among miners and to what degree such use contributes to accidents and injuries.

Under the proposed rule, MSHA would require policy violation information (including drug-testing results) be kept consistent with existing record retention requirements. The agency seeks comments about what records would need to be kept and for how long a period of time.

In addition, it is proposed that post-accident test results would be required to be included in reports of injuries and accidents as well as fatalities.

Although MSHA is not currently proposing specific changes to 30 CFR part 50, it is the intent to consider how best to reflect the results of post-accident drug-testing. In order to assess whether alcohol or drugs have been identified as contributing causes of accidents in the past and to understand how evidence of such use was addressed in accident reports, a review was conducted of those identifiable available fatal and non-fatal accident reports where alcohol or drugs were mentioned. Although it was not possible to determine with certainty, this examination suggested that there are more accidents (both fatal and non-fatal) than reflected in reports where alcohol or drugs are a contributing or root cause. This is based on the observation that, in both the non-fatal and fatal accident reports, there was a lack of uniformity concerning how alcohol and/or drug factors were considered and reported. Specifically, there was no regularity as to:

- Procedures and/or criteria for investigating the role of alcohol/drugs;
- The type of information provided from the investigations concerning alcohol/drugs; and
- How the information about alcohol/drugs is reported (*i.e.*, there is no standard template).

Since the mining industry currently lacks a uniform policy concerning when alcohol- and/or drug-testing is conducted after accidents or injuries, it is not surprising that there is inconsistent reporting of such data. Making alcohol- and drug-tests a standard part of an accident investigation and reporting the results could go a long way toward providing better information about the extent to which alcohol and drug use contributes to accidents in the mining industry. However, the test results alone will not sufficiently determine the role of a substance in an accident. Rather, the industry must consider the test results in light of the facts of the accident and the effects of the particular substance in question. To fully understand the role of alcohol or drugs, it might be helpful to develop a standard set of procedures/criteria for investigating the role of alcohol/drugs in non-fatal and fatal accidents and establish a taxonomy structure for information gathering and reporting.

In addition, investigators may lack the level of expertise needed to reliably:

- Identify alcohol and drug ''evidence'' at the post-accident scene;
- Interpret the meaning of alcohol- and drug-test results; and
- Assess whether identified alcohol/drug involvement and their effects could have contributed to the fatality outcome by affecting behaviors such as attention, concentration, judgment, decision-making, or motor skills.

Therefore, it might be helpful to more systematically capture and report how alcohol and/or drugs are identified/tested positive, even when not deemed to be a contributory or root cause. Furthermore, an explanation of why the alcohol/drug use was ruled out or discounted would be informative. Finally, it may be useful to provide training to investigators so that they recognize signs that alcohol and/or drugs may have been involved and know what questions to ask about possible involvement when investigating accidents. MSHA invites comments about how best to reflect post-accident test results in required reports following both fatal and non-fatal accidents.

V. Executive Order 12866

Executive Order (E.O.) 12866 requires that regulatory agencies assess both the costs and benefits of regulations. To comply with this requirement, MSHA has prepared a Preliminary Regulatory Economic Analysis (PREA) for this proposed rule. The PREA examines the costs and benefits of the proposed requirements for coal and metal/non metal (M/NM) mine operators to establish an alcohol- and drug-free mine program that includes a written policy, employee education, supervisory training, alcohol- and drug-testing for miners who perform safety-sensitive job duties and their supervisors, referrals to assistance for miners who violate the policy, and recordkeeping provisions. General administrative and clerical personnel are not covered by these proposed requirements.

The PREA also contains supporting data and explanation for the summary economic materials presented in this preamble, including data on the mining industry, feasibility, small business impacts, and paperwork. The PREA is located on MSHA's Web site at *http://www.msha.gov/REGSINFO.HTM.* A copy of the PREA can be obtained from MSHA's Office of Standards, Regulations and Variances at the address in the **ADDRESSES** section of the preamble. MSHA requests comments on all the estimates of costs and benefits present in this PREA and on the data and assumptions the agency used to develop estimates.

Under E.O. 12866, a significant regulatory action is one meeting any of a number of specified conditions, including the following: Having an annual effect on the economy of $100 million or more, creating a serious inconsistency or interfering with an action of another agency, materially altering the budgetary impact of entitlements or the rights of entitlement recipients, or raising novel legal or policy issues. Based on the PREA, MSHA has determined that this proposed rule would not have an annual effect of $100 million or more on the economy; therefore, it is not an economically significant regulatory action. However, MSHA has concluded that the proposed rule is otherwise significant because it raises novel legal or policy issues.

A. Population at Risk

The proposed rule establishes new standards for all mine operators. With respect to the coal mining industry, the proposed rule would apply to 2,013 coal mines employing 80,256 miners and to 2,966 coal contractors with an additional 36,227 non-office employees, using MSHA's Office of Program Evaluation and Information Resources (PEIR) data for 2007. With respect to the M/NM mines, the proposed rule would apply to 12,773 M/NM mines employing 159,644 miners and to 5,302 M/NM contractors with an additional 64,333 non-office employees, using PEIR data for 2007. Office workers who have only clerical or administrative duties are not covered by the proposed requirements for drug-testing or training. In total, this rule would apply to approximately 23,054 mine operators (*i.e.*, mines and contractors) and 340,460 miners (*i.e.*, miners and non-office employees of contractors).

B. Benefits

The use of alcohol and drugs in the workplace negatively affects U.S. industry through lost productivity, workplace accidents and injuries, employee absenteeism, low morale, and increased illness. The loss to U.S. companies due to employees' alcohol and drug use and related problems is estimated at billions of dollars per year. This proposed rule would require mine operators to establish an alcohol- and drug-free workplace program to prevent workplace accidents, injuries and fatalities in mines caused by the use or abuse of alcohol and/or drugs.

MSHA currently prohibits the use of intoxicating beverages and narcotics in or around M/NM mines; and persons under the influence of alcohol or narcotics are not permitted on the job site. However, since these requirements only apply to M/NM operators, MSHA believes that uniform policies and procedures are needed to prevent the misuse of alcohol and drugs that could impair the functioning of miners and result in the injury or death in both coal and M/NM mines.

A major benefit from this rulemaking would be the prevention of injuries and fatalities resulting from accidents caused by neglect or error on the part of individuals whose judgment or motor skills may be impaired by the use of alcohol and/or drugs. MSHA's reporting process does routinely include inquiries into the use of alcohol or drugs as contributing factors in mine accidents. Consequently, there may have been accidents in which alcohol or drugs were involved but were not reported to inspectors or identified during MSHA investigations. A preliminary review by MSHA of fatal and non-fatal mine accident records revealed a number of instances in which alcohol, drugs, or drug paraphernalia were found or reported at the scene, or where the post-accident toxicology screens of those involved in an accident revealed the presence of alcohol or drugs.

The U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration's (SAMHSA) 2006 National Survey on Drug Use and Health [26] reports that in 2006, of the 17.9 million current illicit drug [27] users age 18 and over, 13.4 million (74.9 percent) were employed.[28] Similarly, among 54 million adult binge drinkers, 42.9 million (79.4 percent) were employed, and among 16.3 million persons reporting heavy alcohol use, 12.9 million (79.2 percent) were employed.[29] Also, in 2006, of the 20.6

[26] The 2006 National Survey on Drug Use and Health (NSDUH) is the annual survey and primary source of information on the use of illicit drugs, alcohol, and tobacco in the civilian, non-institutionalized population of the United States aged 12 years old or older.

[27] The survey defined current illicit drug use as the non-medical use of marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants or prescription-type drugs. Non-medical use is defined as the use of prescription-type drugs not prescribed for the respondent by a physician or used only for the experience or feeling they caused. Non-medical use of any prescription-type pain reliever, sedative, stimulant, or tranquilizer does not include over-the counter drugs. Non-medical use of stimulants includes methamphetamine use.

[28] Substance Abuse and Mental Health Services Administration. (2007). *Results from the 2006 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H–32, DHHS Publication No. SMA 07–4293). Rockville, MD.

[29] Ibid.

million adults classified with substance dependence or abuse, 12.7 million (61.5 percent) were employed full-time.[30] Furthermore, among the U.S. working age population (ages 18–64) diagnosed with a substance use disorder, 62.7 percent were employed full-time.[31]

In a 1998 analysis of available toxicology reports across a variety of occupations and within different industries, the Bureau of Labor Statistics (BLS) estimated that as many as one in five workplace fatalities had a positive test for alcohol or drugs.[32] BLS reported that alcohol was the substance found most often, appearing in 48 percent of positive reports.[33]

SAMHSA's June 2007 *Worker Substance Use and Workplace Policies and Programs* Report [34] shows alcohol and drug use and abuse by standard occupational and industry classifications. Illicit drug use was reported at 15.1 percent and heavy alcohol use was 17.8 percent among full-time workers aged 18–64 in the construction, trade, and excavation occupational group.[35] The data also show that in the mining [36] industry, 13.3 percent of full-time miners were heavy alcohol users and 7.3 percent admitted that they used illicit drugs within the past month. This does not mean that those surveyed admitted to either being under the influence or having used alcohol or drugs at work or immediately prior to work. However, the statistics do suggest a cause for employer concern since there are no guarantees that those who drink heavily or use illicit drugs would constrain such behaviors, which have the potential to seriously jeopardize mine safety, to off-duty hours. Many firms find that addressing alcohol and drug use is well worth the time and money involved in a drug-testing program. For example, after MSHA published its 2005 ANPRM, an industry representative said, ''The principle benefit is it's a safe workplace due to employees operating out of the influence of drugs or alcohol.'' A commenter from a trade association said, ''The costs to a mine operation of substance abuse in worker health and safety, as well as production losses, are already a powerful incentive to maintain an effective substance abuse program.''

The purpose of the requirements in the proposed rule is to establish alcohol- and drug-free mine programs in all mine operations. These programs are designed to help prevent accidents, injuries, and fatalities resulting from the misuse of alcohol and use of prohibited drugs by miners who perform safety-sensitive job duties on mine property. An alcohol- and drug-free mine program that includes a written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive job duties and their supervisors, and referrals to assistance for miners who violate the policy, would decrease injuries and fatalities. The number of fatalities associated with alcohol or drugs is difficult to quantify due to a lack of consistency in reporting the possibility of alcohol or drug involvement in injuries and fatalities.

MSHA's analysis of fatal accidents from 1975 to 2007 revealed that 24 of 978 reported deaths involved alcohol or drugs. From 1983 through 2007, there were 593,047 non-fatal accidents reported, with 56 possibly involving alcohol or drugs. MSHA believes these figures under-represent the negative effects of alcohol and drugs in the mines because of a current lack of uniformity in investigation and particularly in reporting procedures.

Mine operators are not currently required to have an alcohol- and drug-free mine program for preventing the use of alcohol and drugs that could impair the function of miners and result in the injury or death of themselves or their coworkers. However, MSHA believes this proposed rule would benefit both mine operators and miners in the following ways:

(1) Mine operators would not have to hire new miners who cannot pass a pre-employment test, so all mine operators would benefit from not hiring persons shown to misuse alcohol and/or drugs. (2) Small mines in particular would benefit by implementing drug-testing procedures, since many small mines currently do not test for drug use and hence employ those unable to pass pre-employment drug-tests required by larger mines. (3) All mine operators across the country would be subject to consistent requirements. (4) Miners would benefit by having job security in the event that they self-disclose an alcohol or drug problem or seek treatment upon their first positive alcohol-or drug-test.

Not implementing this rule would allow accidents related to alcohol and drugs, including cases where innocent co-workers are harmed, to continue to be underreported and possibly allow accidents related to alcohol and drugs to go unabated.

C. Compliance Costs

MSHA estimated the first-year costs and the annual recurring costs of the proposed rule. MSHA estimated costs to mine operators on the following proposed provisions: Establish an alcohol- and drug-free mine program that includes a includes a written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive duties and their supervisors, referrals to assistance for miners who violate the policy, and record retention.

MSHA estimates that the total cost for the initial year of the proposed rule would be approximately $16,008,983 for all coal and M/NM mine operators and mine contractors. Of the $16.0 million, MSHA estimates approximately $1,253,065 in costs are related to the establishment of an alcohol- and drug-free mine program that includes a written policy, $7,150,544 in costs are for the alcohol- and drug-testing; $6,840,971 in costs are related to training requirements, and $764,402 are related to the record retention provisions. Table 1 provides a summary of the approximate first year costs of the proposed rule by mine size and proposed provision.

[30] Ibid.

[31] Ibid.

[32] Weber, W., and Cox, C. ''Work-Related Fatal Injuries in 1998'' Compensation and Working Conditions, Spring 2001, pp. 27–29.

[33] Ibid.

[34] Substance Abuse and Mental Health Services Administration (2007). *The Worker Substance Use and Workplace Policies and Programs Report* presents findings on substance use among workers and on workplace drug policy and programs from the 2002, 2003, and 2004 National Surveys of Drug Use and Health. (Office of Applied Studies, Analytic Series: A–29).

[35] The Standard Occupation System categorizes occupations into 21 groups. The Construction Trades and Extraction Workers group includes mining.

[36] The NAICS, which replaced the Standard Industry Classification (SIC), categorizes all industries into 19 major groups and is used to classify industries in the *Report*.

TABLE 1—SUMMARY OF THE APPROXIMATE FIRST YEAR COSTS

Proposed provisions	Employees			Total first year costs
	1–19	20–500	501+	
Written policy	$1,074,099	$178,490	$476	$1,253,065
Alcohol and drug testing	2,479,298	4,512,894	158,352	7,150,544
Training	2,291,625	4,396,829	152,517	6,840,971
Recordkeeping	309,012	401,312	54,079	764,403
Total First Year Costs	6,154,034	9,489,524	365,424	16,008,983

MSHA estimated annual recurring cost thereafter for all mine operators and contractors is $13,008,951. Of the $13.0 million, MSHA estimates approximately $7,150,544 in costs are for the alcohol- and drug-testing; $5,094,004 in costs are related to training requirements, and $764,402 are related to the record retention provisions. Table 2 provides a summary of the approximate annual recurring costs of the proposed rule by mine size and proposed provision.

TABLE 2—SUMMARY OF THE APPROXIMATE ANNUAL RECURRING COSTS

Proposed provisions	Employees			Total annual recurring costs
	1–19	20–500	501+	
Alcohol and drug testing	$2,479,298	$4,512,894	$158,352	$7,150,544
Training	1,712,395	3,268,844	112,765	5,094,004
Recordkeeping	309,012	401,312	54,079	764,403
Total Annual Recurring Costs	4,500,705	8,183,050	325,196	13,008,951

D. Feasibility

MSHA has concluded that the requirements of the proposed rule are technologically and economically feasible within the coal and M/NM mining sectors.

This proposed rule is not a technology-forcing standard and does not involve activities on the frontier of scientific knowledge. In addition, the proposed rule would not require the purchase of any machinery or equipment to implement these standards. Therefore, we have concluded that this proposed rule is technologically feasible.

The estimated compliance cost of the proposed rule for all mines in the first year is $16.0 million and in subsequent years the annual recurring cost is approximately $13.0 million, which is 0.00016 percent and 0.00013 percent, respectively, of its annual revenue of $99.4 billion. MSHA concludes that the final rule would be economically feasible for both the coal and M/NM industries because the annual recurring compliance costs are well below one percent of the estimated annual revenue for all mines.

VI. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

In accordance with the Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), MSHA has analyzed the impact of the proposed rule on small entities. Based on the analysis, MSHA certifies that the proposed rule does not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is presented in the PREA and summarized below.

A. Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration's (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not established an alternative definition, and hence is required to use the SBA's definition. The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees (13 CFR 121.201). This analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities.'' MSHA concludes that it can certify that the final rule would not have a significant economic impact on a substantial number of small entities.

B. Factual Basis for Certification

MSHA's analysis of the economic impact on ''small entities'' begins with a ''screening'' analysis. The screening compares the estimated cost of a rule for small entities to the estimated revenue. When the estimated cost is less than one percent of estimated revenue (for the size categories considered), MSHA believes it is generally appropriate to conclude that the proposed rule does not have a significant economic impact on a substantial number of small entities. If estimated costs are equal to or exceed one percent of revenues, MSHA would investigate whether further analysis is required.

Coal Mine Revenues

Revenues for coal mines are derived from data on underground and surface coal prices and tonnage. Total underground coal production in 2007 was approximately 349 million tons. The 2006 price of underground coal was $38.28 per ton.[37] To estimate the 2007 price, the 2006 price was increased by 5.5 percent to $40.37, using the Bureau of Labor Statistics producer price index for underground bituminous coal. Total estimated revenue in 2007 for underground coal production was $14.1 billion. Multiplying tons by the 2007 price per ton, 2007 underground coal revenue, by mine size, is $11.2 billion for mines with 1–500 employees.

Total surface coal production in 2007 was approximately 792 million tons. The 2006 price of surface coal was $18.88 per ton.[38] To estimate the 2007

[37] U.S. DOE, EIA, ''Annual Coal Report 2006,'' Table 28, October 2007.

[38] Ibid.

price, the 2006 price was increased by 8.7 percent to $20.52, using the Bureau of Labor Statistics producer price index for surface bituminous coal. Total estimated revenue in 2007 for surface coal production was $16.2 billion. Multiplying tons by the 2007 price per ton, 2007 surface coal revenue, by mine size, is $11 billion for mines with 1–500 employees.

Underground and surface coal revenue is estimated to be approximately $22.2 billion for mines with 1–500 employees. Underground and surface coal revenues for all mines are estimated to be $30.3 million.

M/NM Mine Revenues

Total 2007 revenues for M/NM mines are estimated to be $68 billion. Total M/NM 2007 employment hours are 362,707,747. Estimated revenues were divided by employment hours to arrive at an average of $187.48 revenue per hour. Revenue for surface M/NM mines with 1–500 employees is approximately $54.8 billion (292.6 million employment hours × $187.48). Revenue for underground M/NM mines with 1–500 employees is approximately $5.1 billion (27.2 million employment hours × $187.48). Thus, revenues for surface and underground mines with 1–500 employees are estimated to be $59.9 billion.

Results of Screening Analysis

The compliance cost of the proposed rule for coal mines and M/NM with 1–500 employees as a percent of revenues is 0.0192 percent for the first year and 0.0156 percent for ongoing years. This suggests that the proposed rule would not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act

This NPRM contains information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The title, description, and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance.

Description: Alcohol- and Drug-Free Mines: Policy, Prohibitions, Testing, Training, and Assistance establishes a requirement for mine operators to set up alcohol- and drug-free mine programs that include a written policy, employee education, supervisory training, alcohol- and drug-testing for miners that perform safety-sensitive job duties and their supervisors, and referrals to assistance for miners who violate the policy. The proposed rule would also require those who violate the prohibitions to be removed from the performance of safety-sensitive job duties until they complete the recommended treatment and their alcohol- and drug-free status is confirmed by a return-to-duty test. These guidelines are established under authority of 30 U.S.C. 811.

The proposed rule establishes paperwork requirements at section 66.201 and subpart F. In addition, certain paperwork requirements at section 66.300 are incorporated by reference from title 49 CFR part 40, *Procedures for Transportation Workplace Drug and Alcohol Testing Programs.*

This proposed rule requires that mine operators establish and implement a written alcohol- and drug-free mine policy and requires mine operators to keep and retain test records. The policy that can be based on a model provided by MSHA and posted in common areas accessible to miners should inform workers of the prohibitions against alcohol and drug use; the consequences for their use; and the existence of training requirements for certain miners and what those training requirements are. In addition, mine operators are required to maintain records of the following information: The number of workers in safety-sensitive positions; the total number of miners tested; the number of verified positive alcohol and drug tests for each substance; which miners were tested; testing dates; and test results. Mine operators are also required to maintain records of instances in which post-accident or reasonable suspicion testing is not conducted within the timeframes required by the rule. Such records should include an explanation of the reasons why testing was not conducted as required. Mine operators would be required to retain these records for at least three years.

By incorporating title 49 CFR part 40 by reference, these guidelines also require the OMB-approved federal Custody and Control Form (CCF) to document the integrity and security of alcohol- and drug-testing specimens from the time of collection through analysis.

Description of Respondents: Mine operators/or service agents acting on behalf of affected mine operators.

Response Burden Estimate: We anticipate the total annual response burden imposed by these guidelines to be 72,791 hours for the initial year and 49.737 hours per year thereafter. The initial year burden estimate is based on the following: (1) A mine owner is estimated to require an average of one hour to develop and post the required drug-free workplace policy using the MSHA sample. Based on a total of 23,054 mines, this results in 23,054 burden hours for development and posting of the policy. (2) The annual maintenance for non-substantive changes of the written policy is estimated at 0.167 burden hours per mine. Based on a total of 23,054, this results in 3,850 burden hours. (3) The annual recordkeeping to maintain test records is estimated at 0.167 burden hours per mine. Based on a total of 23,054 mines, this results in 3,850 burden hours for recordkeeping and retention. (4) We estimate the completion of 201,618 Alcohol Testing Forms and federal Custody and Control Forms each year. This is based on a total miner population of 340,460 with 10 percent of the population being subjected to random testing for alcohol and drugs and about 20 percent being subjected to other forms of testing for alcohol and drugs that include pre-employment, post-accident, reasonable suspicion, return-to-duty, and follow-up testing. The average response burden for the Alcohol Testing Forms is estimated at 0.167 burden hours per mine. This results in 16,835 burden hours (0.167 hours per form × 100,809 forms). The average response burden for completion of the federal Custody and Control Forms is estimated by the U.S. Department of Health and Human Services as 0.25 burden hours per form, computed as follows: 5 minutes for each donor (miner), 4 minutes for the collector, 3 minutes for the laboratory, and 3 minutes for the Medical Review Officer. This results in 25,202 hours of burden (0.25 hours per form × 100,809 forms).

The subsequent year estimate of 49,737 burden hours, where the burden associated with the development of the written policy is excluded, is based on 3,850 hours to maintain the written policy, 3,850 hours for recordkeeping and retention, 16,835 hours for completion of the Alcohol Testing Form and 25,202 hours for completion of the federal Custody and Control Form.

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the

burden. MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

VIII. Other Regulatory Considerations

A. The Unfunded Mandates Reform Act of 1995

MSHA has reviewed the proposed rule under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). MSHA has determined that the proposed rule would not include any federal mandate that may result in increased expenditures by state, local, or tribal governments, and it would not increase private-sector expenditures by more that $100 million in any one year or significantly or uniquely affect small governments. Accordingly, the Unfunded Mandates Reform Act of 1995 requires no further agency action or analysis.

B. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

This proposed rule will have no effect on family well-being or stability, marital commitment, parental rights or authority, or income or poverty of families and children. Accordingly, section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires no further agency action or analysis.

C. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

This proposed rule would not implement a policy with takings implications. Accordingly, E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, requires no further agency action or analysis.

D. Executive Order 12988: Civil Justice Reform

This proposed rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the federal court system. Accordingly, this proposed rule meets the applicable standards provided in section 3 of E.O. 12988, Civil Justice Reform.

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule would have no adverse impact on children. Accordingly, E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks, as amended by E.O. 13229 and 13296, requires no further agency action or analysis.

F. Executive Order 13132: Federalism

The proposed rule would not have ''federalism implications'' because it would not ''have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.'' Accordingly, E.O. 13132 requires no further agency action or analysis.

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

This proposed rule would not have ''tribal implications'' because it does not ''have substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' Accordingly, E.O. 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule has been reviewed for its impact on the supply, distribution, and use of energy because it applies to the underground coal mining sector. This proposed rule will not impose any ''significant energy action'' because it will not be ''likely to have a significant adverse effect on the supply, distribution, or use of energy * * * (including a shortfall in supply, price increases, and increased use of foreign supplies).'' Accordingly, E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, requires no further agency action or analysis.

I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has reviewed the proposed rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA has determined and certified that the proposed rule does not have a significant economic impact on a substantial number of small entities.

List of Subjects

30 CFR Part 56

Chemicals, Electric power, Explosives, Fire prevention, Hazardous substances, Metals, Mine safety and health, Noise control, Reporting and recordkeeping requirements.

30 CFR Part 57

Chemicals, Electric power, Explosives, Fire prevention, Gases, Hazardous substances, Metals, Mine safety and health, Noise control, Radiation protection, Reporting and recordkeeping requirements.

30 CFR Part 66

Alcohol- and drug-testing, Mine safety and health, Reporting and recordkeeping requirements.

Dated: August 28, 2008.

Richard E. Stickler,

Acting Assistant Secretary for Mine Safety and Health.

For the reasons set forth in the preamble, and under the authority of the Federal Mine Safety and Health Act of 1977, MSHA is proposing to amend chapter I of title 30 of the Code of Federal Regulations as follows.

PART 56—SAFETY AND HEALTH STANDARDS—SURFACE METAL AND NON METAL MINES

1. The authority citation for part 56 continues to read as follows.

Authority: 30 U.S.C. 811.

Subpart S [Amended]

§ 56.20001 [Removed and Reserved]

2. Remove and reserve § 56.20001.

PART 57—SAFETY AND HEALTH STANDARDS—UNDERGROUND METAL AND NON METAL MINES

3. The authority citation for part 57 continues to read as follows.

Authority: 30 U.S.C. 811.

Subpart S [Amended]

§ 57.20001 [Removed and Reserved]

4. Remove and reserve § 57.20001.

5. A new subchapter N and a new part 66 are added to title 30 of the Code of Federal Regulations to read as follows.

30 CFR Subchapter N—Uniform Mine Safety Regulations

PART 66—ALCOHOL- AND DRUG-FREE MINES: POLICY, PROHIBITIONS, TESTING, TRAINING, AND ASSISTANCE

Sec.

Subpart A—General

66.1 Purpose.
66.2 Applicability.
66.3 Definitions.

Subpart B—Prohibitions

66.100 Prohibited substances.
66.101 Prohibited behaviors.

Subpart C—Alcohol- and Drug-Free Mine Program Requirement

66.200 Purpose and scope.
66.201 Written policy.
66.202 Education and awareness program for miners.
66.203 Training program for supervisors.
66.204 Miner assistance following admission of use of prohibited substances.

Subpart D—Alcohol- and Drug-Testing Requirements

66.300 Purpose and scope.
66.301 Substances subject to mandatory testing.
66.302 Additional testing.
66.303 Circumstances under which testing will be required.
66.304 Pre-employment testing.
66.305 Random testing.
66.306 Post-accident testing.
66.307 Reasonable suspicion testing.

Subpart E—Operator Responsibilities, Actions, and Consequences

66.400 Consequences to miner for failing an alcohol or drug test or refusal to test.
66.401 Operator actions pending receipt of test results.
66.402 Substantiating legitimate use of otherwise prohibited substances.
66.403 Operator actions after receiving verified test results.
66.404 Evaluation and referral.
66.405 Return-to-duty process.
66.406 Return-to-duty and follow-up testing.

Subpart F—Recordkeeping and Reporting

66.500 Recordkeeping requirements.

Authority: 30 U.S.C. 811.

30 CFR Subchapter N—Uniform Mine Safety Regulations

PART 66—ALCOHOL- AND DRUG-FREE MINES: POLICY, PROHIBITIONS, TESTING, TRAINING AND ASSISTANCE

Subpart A—General

§ 66.1 Purpose.

This part establishes the requirements for mine operators to develop an alcohol- and drug-free mine program to prevent accidents, injuries, and fatalities resulting from the misuse of prohibited substances by miners performing safety-sensitive job duties and their supervisors. Alcohol- and drug-free mine programs established prior to the effective date of this rule that include consistent policies, and alcohol- and drug-testing programs, and provide at least the same level of protection as these requirements, are in compliance with this standard.

§ 66.2 Applicability.

(a) The possession or misuse of prohibited substances, except when used according to a valid prescription, is prohibited for all persons on and around mine property.

(b) The alcohol- and drug-testing provisions in subpart D apply only to those miners who perform safety-sensitive job duties. Management and administrative personnel who supervise the performance of safety-sensitive job duties are also considered to hold safety-sensitive positions; however, general administrative and clerical personnel are not. Such determinations shall be made consistent with the requirements of 30 CFR parts 46 and 48 for who must take comprehensive miner training.

(c) Mine operators must inform all miners and contractors who perform work on their mine property of the requirements under this rule.

§ 66.3 Definitions.

As used in this part:

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a concentration so high that it is not consistent with human urine.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol, or other low molecular weight alcohols including methyl and isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part. This provides an indication of the blood alcohol concentration (BAC) level which is equated with impairment levels.

Breath Alcohol Technician (BAT). A person who instructs and assists miners in the alcohol-testing process and operates an evidential breath testing device. A BAT can be an employee of the mine operator. A BAT must have received qualifications training that includes training in alcohol-testing procedures and the operation of alcohol-testing devices.

Confirmed drug test. A confirmation test result received by a Medical Review Officer (MRO) from a laboratory.

Cut-off levels. The cut-off concentration of drug metabolite that is used for each drug class to call a urine specimen negative or positive. Based on the cut-off concentration used for each different drug class, a negative specimen is any specimen that contains no drug or whose apparent concentration of drug or drug metabolite is less than the cut-off concentration used for that drug or drug class.

Drug-free workplace program. A program that prohibits the possession or misuse of prohibited substances while working and includes five elements (written policy, education, training, testing, and referrals for assistance) designed to prevent impairing effects that can compromise workplace safety. This term is used interchangeably with an ''alcohol- and drug-free workplace program'' and ''drug-free mine program.''

Employee Assistance Program (EAP). A worksite-focused program designed to assist in the identification and resolution of problems associated with personal problems, such as alcohol and/or drug abuse.

Follow-up testing. A minimum of six unannounced tests performed in the first 12 months on any miner who returns to safety-sensitive job duties after violating the alcohol- and drug-free workplace policy.

Initial drug test. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Laboratory. A U.S. laboratory certified by the U.S. Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA) as meeting the minimum standards of subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs and which is also certified by the College of American Pathologists (CAP) to perform Forensic Urine Drug Testing (FUDT).

Medical Review Officer (MRO). A licensed physician who is responsible for receiving and reviewing laboratory results generated by a mine operator's drug-testing program and evaluating medical explanations for certain drug test results. An MRO can be an employee of the mine operator or a service agent.

Persons performing safety-sensitive job duties. Those who perform job activities that are inherently dangerous on a regular and/or recurring basis and are required under 30 CFR parts 46 and 48 to take comprehensive miner training. Management and administrative personnel who supervise persons performing safety-sensitive job duties are also considered to perform safety-sensitive job duties. Therefore, throughout the rest of this part, the term ''miner'' is used to include such supervisors. General administrative and clerical personnel are not considered to perform safety-sensitive job duties.

Post-accident testing. Testing for the misuse of alcohol or drugs that is triggered either by an occupational injury or an accident that is done to help determine whether alcohol and/or drugs were a factor in the injury or accident.

Pre-employment testing. For alcohol: Testing of applicants after a conditional offer of employment has been made but prior to the first performance of safety-sensitive job duties. *For drugs:* Testing of applicants prior to the first performance of safety-sensitive job duties, irrespective of whether a conditional offer of employment has been made.

Prohibited substances. Alcohol, and the following controlled substances, except when used according to a valid prescription: Amphetamines (including methamphetamines), barbiturates, benzodiazepines (*e.g.*, Valium, Librium, Xanax), cannibinoids (marijuana/THC), cocaine, methadone, opiates (*e.g.*, heroin, opium, codeine, morphine), phencyclidine (PCP), propoxyphene (*e.g.*, Darvon), synthetic/semi-synthetic opioids (*i.e.*, hydrocodone, hydromorphone, oxymorphone, oxycodone) and any other controlled substances designated by the Secretary.

Random testing. Unannounced testing of miners assigned to safety-sensitive job duties for use of alcohol or drugs selected through a scientifically arbitrary process without regard to personal identifying information.

Reasonable suspicion testing. Testing for alcohol or drugs conducted when a supervisor documents observable signs and symptoms that lead the supervisor to suspect alcohol or drug use in violation of the alcohol- and drug-free workplace policy.

Return-to-duty testing. Testing performed on any miner before resuming safety-sensitive job duties after having failed to test negative for alcohol or drugs, or following admission of alcohol or drug use and after satisfactory completion of education and/or treatment prescribed by a Substance Abuse Professional (SAP).

Safety-sensitive job duties. Any type of work activity where a momentary lapse of critical concentration could result in an accident, injury, or death.

Service agent. Any person or entity possessing the required qualifications and/or certifications, other than an employee of the mine operator, who provides services specified under this part to mine operators in connection with MSHA alcohol- and drug-testing requirements, including but not limited to collectors, laboratories, MROs, Substance Abuse Professionals, or BATs.

Split specimen. In drug-testing, a part of the urine specimen that is sent to the laboratory but not analyzed. Rather, it is retained unopened so that it can be sent to a second laboratory in the event that a miner requests that it be tested because he or she disputes the results reported by the first laboratory and verified by the MRO.

Substance Abuse Professional (SAP). A specially trained and qualified person who evaluates miners who have violated a mine operator's alcohol- and drug-free workplace policy and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. A specimen with creatinine and specific gravity values that are so diminished that they are not consistent with human urine.

Verified test. A drug-test result or validity testing result from a laboratory that has undergone review and final determination by an MRO.

Subpart B—Prohibitions

§ 66.100 Prohibited substances.

(a) Prohibited substances, except when conditions of paragraph (b) of this section are met, shall not be permitted or used on or around mine property.

(b) Miners who possess or have used a prohibited substance will not be in violation of this part provided that an MRO has determined that the miner has a valid prescription for the substance and is using it as prescribed.

§ 66.101 Prohibited behaviors.

(a) Miners determined to have used a prohibited substance and/or to be under the influence of a prohibited substance as defined by § 66.3(p) shall not be allowed to perform safety-sensitive job duties.

(b) Specifically, miners must not report for duty or remain on duty if they:

(1) Are under the influence or impaired by alcohol as verifiable by a Blood Alcohol Concentration (BAC) of 0.04 percent or greater; or

(2) Have used a prohibited substance as verifiable by a positive drug test, unless an MRO has determined that the miner has a valid prescription for the prohibited substance and is using it as prescribed; or

(3) Have refused to submit to a drug or alcohol test or have adulterated or substituted his/her specimen in any such test.

Subpart C—Alcohol- and Drug-Free Mine Program Requirement

§ 66.200 Purpose and scope.

The mine operator shall establish a written alcohol- and drug-free mine program that includes a written policy, an education and awareness program for nonsupervisory miners, a training program for supervisors, alcohol- and drug-testing, and referrals for assistance for miners who violate this rule.

§ 66.201 Written policy.

(a) The alcohol- and drug-free mine program shall contain a written policy statement that shall be provided to all employees/miners and will inform them of the purpose of the policy; the prohibitions against the possession or use of prohibited substances; alcohol- and drug-testing requirements; the consequences of policy violations; and training requirements. The policy will also reference these regulations and identify which miners are subject to the alcohol- and drug-testing provisions.

(b) A mine operator must ensure that every miner has been informed of the policy. The proposed rule requires that a mine operator must provide a copy of the written policy to the miners' representative or post the policy on a bulletin board in a common area in the event that the miners do not have a representative. Mine operators may also choose to distribute the policy during the alcohol- and drug-free awareness training sessions or distribute the policy in an electronic format; however, these additional means of distribution are not required.

(c) Mine operators may use the sample model policy statement available from MSHA or from the Web site at *http://www.msha.gov.*

§ 66.202 Education and awareness program for nonsupervisory miners.

(a) Mine operators are required to provide education and awareness programs for nonsupervisory miners that meet the following requirements:

(1) Each newly hired miner must receive a minimum of 60 minutes of training before such miner is assigned to safety-sensitive job duties. The training must inform them of:

(i) The mine's alcohol- and drug-free mine policy, including alcohol- and drug-testing requirements;

(ii) The dangers of alcohol and drug use and the impact of such use on safety in the mine;

(iii) Actions to take when others are suspected of violating the policy; and

(iv) Information about any available drug counseling, rehabilitation, and employee assistance programs (EAPs).

(2) All nonsupervisory miners, on an annual basis, will receive a minimum of 30 minutes of training to review the elements in paragraph (a)(1) of this section.

(3) Training must be delivered by a competent person knowledgeable about workplace substance abuse, these regulatory requirements, and the mine operator's policy. Mine operators may use the training materials available from MSHA or the Web site at *http://www.msha.gov.*

(b) Training may be supplemented by written informational materials, including a list of company or community resources that miners can contact for assistance. Videos or other audio-visual materials may be used to supplement interactive training but cannot serve as the sole means of training.

(c) The training requirements in this part can be delivered as part of other new miner and annual nonsupervisory miner refresher training required under parts 46 and 48 of this chapter but must be delivered in addition to the other topics required and cannot displace other existing requirements of parts 46 and 48 of this chapter.

§ 66.203 Training program for supervisors.

(a) A training program for supervisors is required and must meet the following requirements:

(1) Every supervisor authorized by the mine operator to make reasonable suspicion and post-accident testing determinations shall receive an initial two hours of training and one hour annually, that, at a minimum:

(i) Reviews the topics covered in the nonsupervisory miner training described in § 66.202 (a)(1)(i) through (iv);

(ii) Makes them aware of their role in enforcing the alcohol- and drug-free workplace policy;

(iii) Reviews the physical, behavioral, and performance indicators of probable drug use or alcohol misuse and prepares them to recognize and adequately document their observation of these signs of alcohol or drug impairment;

(iv) Trains them to make reasonable suspicion determinations and what procedures to follow when such determinations are made;

(v) Trains them to make post-accident determinations and what procedures to follow when such determinations are made;

(vi) Trains them to make referrals to Substance Abuse Professionals or Employee Assistance Professionals and/or to community resources if they suspect a miner has an alcohol or drug problem but there has not been a known violation of the policy and there is insufficient evidence to warrant a reasonable suspicion test; and

(vii) Trains them on what constitutes safety-sensitive job duties so that they understand who is subject to drug-testing.

(2) All supervisors, on a annual basis, will receive a minimum of 60 minutes of training to review the elements in paragraph (a)(1) of this section.

(3) Training must be delivered by a competent person knowledgeable about workplace substance abuse, these regulatory requirements, and the mine operator's policy. Mine operators may use the training materials available from MSHA or the Web site at *http://www.msha.gov.*

(b) Training may be supplemented by written informational materials, including a list of company or community resources that miners can contact for assistance. Videos or other audio-visual materials may be used to supplement interactive training but cannot serve as the sole means of training.

§ 66.204 Miner assistance following admission of use of prohibited substances.

(a) Mine operators shall make miners and other employees who admit to the illegitimate and/or inappropriate use of prohibited substances aware of available assistance through an employee or miner assistance program, a Substance Abuse Professional (SAP), and/or other qualified community-based resources.

(b) Miners who voluntarily admit to the illegitimate and/or inappropriate use of prohibited substances prior to being testing and seek assistance shall not be considered as having violated the mine operator's policy but shall be subject to the return-to-duty process specified in subpart E, §§ 66.405–406. However, a positive test result during the return-to-duty process will be considered as a violation of the mine operator's policy.

Subpart D—Alcohol- and Drug-Testing Requirements

§ 66.300 Purpose and scope.

(a) Mine operators shall implement an alcohol- and drug-testing program that is valid, reliable, and protects the privacy and confidentiality of the individual to be tested.

(b) Mine operators must follow the U.S. Department of Transportation's (DOT) requirements found in 49 CFR part 40, Procedures for Transportation Workplace Drug Testing Programs, in which references to ''DOT'' shall be read as ''MSHA'' with the following exceptions: the split sample method of collection shall be used, and use of ''bifurcated'' alcohol level for testing is excluded.

(c) Mine operators are subject to all the requirements and procedures incorporated by part 66 and are responsible for the actions of their officials and representatives, and agents in carrying out these requirements.

(d) Mine operators shall designate those who will be responsible for receiving test results and other communications from the MRO or BAT consistent with the requirements of this part. This designee will also be authorized by the mine operator to take immediate action(s) to remove miners from safety-sensitive job duties, or cause miners to be removed from these covered duties, and to make required decisions in the testing and evaluation processes. Mine operators cannot use contracted service agents to perform these functions.

(e) A mine operator may use service agents to perform any of the other the functions required in this rule but may not designate or use a service agent to make drug-testing decisions or to receive alcohol-or drug-test results on behalf of the mine operator.

(f) A mine operator that uses a service agent is responsible for ensuring that service agents meet all requirements and procedures set forth in DOT's requirements found in 49 CFR part 40, except as modified by paragraph (b) of this section. Only laboratories certified by CAP as well as by HHS/SAMHSA shall be used to test collected samples.

§ 66.301 Substances subject to mandatory testing.

Tests will be conducted for the drugs listed below:

(a) Alcohol,

(b) Amphetamines (including methamphetamines),

(c) Barbiturates,
(d) Benzodiazepines (*e.g.*, Valium, Librium, Xanax),
(e) Cannabinoids (THC/marijuana),
(f) Cocaine,
(g) Methadone,
(h) Opiates (heroin, opium, codeine, morphine),
(i) Phencyclidine (PCP),
(j) Propoxyphene (*e.g.*, Darvon), and
(k) Synthetic/Semi-synthetic Opioids (oxymorphone, oxycodone, hydromorphone, hydrocodone).

§ 66.302 Additional testing.

The Secretary of Labor shall be permitted to designate additional substances for which all mine operators must test.

§ 66.303 Circumstances under which testing will be required.

Testing will be conducted in the following circumstances: Pre-employment; randomly at unannounced times; post-accident if the miner may have contributed to the accident; based on reasonable suspicion that a miner has used a prohibited substance; and as part of a return-to-duty process for miners who have violated the rule.

§ 66.304 Pre-employment testing.

(a) Any applicant for a safety-sensitive position must be tested for the presence of drugs before performing safety-sensitive job duties.

(b) Any applicant for a safety-sensitive position must receive an alcohol test after a conditional offer of employment has been made and before performing safety-sensitive job duties.

(c) The mine operator must treat all miners performing safety-sensitive job duties the same for the purpose of pre-employment alcohol- and drug-testing (*i.e.*, mine operators must not test some miners and not others). If it is unclear whether an applicant will be assigned to such duties, it is at the mine operator's discretion to test all applicants; or test only when it is known that the applicant will be assigned to perform safety-sensitive job duties.

(d) The mine operator must not allow a miner to begin performing safety-sensitive job duties if the result of the miner's test indicates a blood alcohol concentration of more than 0.04 percent or if he/she has used a prohibited substance without a valid prescription.

(e) Any incumbent miner who is to be transferred to a position involving the performance of safety-sensitive job duties must be tested for the presence of alcohol or drugs prior to beginning the performance of safety-sensitive job duties and must receive negative test results.

(f) An incumbent miner that has failed or refused a pre-employment alcohol- and drug-test administered under this part, shall not perform safety-sensitive job duties until that miner provides the mine operator proof of having successfully completed a referral, evaluation, and treatment plan, and tested negative on return-to-duty testing as described in subpart E, §§ 66.405–66.406.

(g) A mine operator shall have the discretion to conduct such testing on incumbent miners who are performing safety-sensitive job duties as of the effective date of this rule as long as all such miners are tested.

§ 66.305 Random testing.

Mine operators must randomly conduct unannounced alcohol and drug tests of their miners as described in paragraphs (a) through (e) of this section:

(a) A mine operator shall use random testing rates for alcohol and drugs of 10 percent. The random pool for unannounced alcohol and drug testing during each calendar year shall consist of miners who perform safety-sensitive job duties and their supervisors.

(b) Miners who are on leave or otherwise absent from the workplace will be tested at the next available opportunity, that is, immediately upon their return to work.

(c) Each mine operator shall ensure that random alcohol and drug tests conducted under this part are unannounced and unpredictable. The dates for administering random tests must be periodic and irregularly scheduled throughout the calendar year. The mine operator has the discretion to determine how frequently testing will occur but it must, at a minimum, meet the 10 percent floor established by this part.

(d) The selection of miners for random alcohol and drug testing shall be made by a scientifically valid method, such as a random number table or a computer-based random number generator that is matched with miners' payroll identification numbers, or other comparable unique identifying numbers. Under the selection process used, each miner shall have an equal chance of being tested each time selections are made.

(e) Each mine operator shall ensure that any miner performing a safety-sensitive duty at the time of the notification ceases to perform the safety-sensitive duty and proceeds to the testing site immediately.

§ 66.306 Post-accident testing.

(a) A mine operator is required to conduct alcohol and drug testing of certain miners after certain accidents or workplace injuries occur. Accidents and injuries requiring post-accident testing include occupational injuries requiring medical treatment beyond first aid and accidents that occur while a miner is operating a piece of equipment or performing a work activity that causes or contributes to an accident, injury, or death. Nothing in this section shall be construed to require the delay of necessary medical attention for the injured following an accident or to prohibit a miner from leaving the scene of an accident for the period necessary to obtain assistance in responding to the accident or to obtain necessary emergency medical care.

(1) *Fatal accidents.* As soon as is practicable following an accident involving the loss of human life, a mine operator shall conduct alcohol and drug tests on each surviving miner involved in any work activity that could have contributed to the accident, injury, or death as determined by the mine operator, using the best information available at the time of the decision. The mine operator shall also be authorized and required to have a toxicology test conducted on the deceased that at a minimum tests for all the substances listed in § 66.301.

(2) *Nonfatal accidents.* As soon as is practicable following an accident or occupational injury not involving the loss of human life, the mine operator shall conduct alcohol and drug tests on each miner involved in any work activity that could have contributed to the accident or injury, as determined by the mine operator, using the best information available at the time of the decision.

(b) A mine operator shall ensure that a miner required to be tested for alcohol under this section is tested as soon as is practical but within eight hours of the accident or injury. If an alcohol test is not administered within eight hours following the accident or injury, the mine operator shall cease attempts to conduct the test and prepare and maintain on file a record stating the reasons that the test was not promptly administered.

(c) A mine operator shall ensure that a miner required to be drug tested under this section is tested as soon as is practical but within 32 hours of the accident or injury. If a drug test is not administered within 32 hours following the accident or injury, the mine operator shall cease attempts to conduct the test and prepare and maintain on file a

record stating the reasons that the test was not promptly administered.

(d) A miner who is subject to post-accident testing who fails to remain readily available for such testing, including notifying the mine operator of his or her location if he or she leaves the scene of the accident prior to submission to such test, must be deemed by the employer to have refused to submit to testing.

(e) The results of blood, urine, or breath tests for the use of prohibited substances conducted by federal, state, or local officials having independent authority for the test, shall be considered to meet the requirements of this section provided such tests conform to the applicable federal, state, or local testing requirements, and that the test results are obtained by the mine operator. Such test results may be used only when the tests have been performed within the applicable time limits (eight hours for alcohol and 32 hours for drugs) and the mine operator has been unable to perform separate post-accident tests within those time periods.

(f) Mine operators shall determine when post-accident testing will be ordered and which miners will be tested. Those making such determinations must have received the necessary training (as specified in subpart C) needed to make such determinations prior to doing so.

(g) If MSHA investigators arrive at the scene of an accident within the 32-hour window and determine that miners not originally given a post-accident test may have contributed to the accident, the MSHA investigator can so order the mine operator to have such testing done at the mine operator's expense.

§ 66.307 Reasonable suspicion testing.

(a) A mine operator shall conduct an alcohol and/or drug test when the mine operator has reasonable suspicion to believe that the miner has misused a prohibited substance.

(b) A mine operator's determination that reasonable suspicion exists shall be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the miner. A supervisor, or other company official who is trained in detecting the signs and symptoms of the misuse of alcohol and/or drugs, must make the required observations.

(c) Testing is authorized under this section only if the observations required by paragraph (b) of this section are made during, immediately preceding, or just after the shift. A mine operator may direct a miner to undergo reasonable suspicion testing immediately before, during, or after the miner is to perform safety-sensitive job duties.

(d) A mine operator shall ensure that a miner required to be tested for alcohol under this section is tested as soon as is practical but within eight hours of the mine operator's determination that reasonable suspicion exists. If an alcohol test is not administered within eight hours, the mine operator shall cease attempts to conduct the test and prepare and maintain on file a record stating the reasons that the test was not promptly administered.

(e) A mine operator shall ensure that a miner required to be tested for drugs under this section is tested as soon as is practical but within 32 hours of the mine operator's determination that reasonable suspicion exists. If a drug test is not administered within 32 hours, the mine operator shall cease attempts to conduct the test and prepare and maintain on file a record stating the reasons that the test was not promptly administered.

(f) Those authorized to make decisions on behalf of the mine operator as to when reasonable suspicion testing will be ordered and which miners will be tested will receive the necessary training needed to make such determinations prior to doing so as specified in subpart C. The mine operator will determine who is authorized to make these decisions.

(g) If the collection site is not on the mine property, miners being tested because of reasonable suspicion should not be allowed to drive themselves to the site, but rather shall be accompanied by authorized mine personnel.

Subpart E—Operator Responsibilities, Actions, and Consequences

§ 66.400 Consequences to miner for failing an alcohol or drug test or refusal to test.

(a) A mine operator, upon a miner's verified positive drug test result, an alcohol test with a result indicating a blood alcohol concentration of 0.04 percent or greater, a refusal to test (including by adulterating or substituting a urine specimen), or any other violation of the mine operator's policy prohibiting possession, impairment from or use of alcohol or drugs must not return the miner to the performance of safety-sensitive job duties until or unless the miner successfully completes the return-to-duty process of §§ 66.405 and 66.406 of this part. The miner may be assigned to duties that are not safety-sensitive at the mine operator's discretion.

(b) Mine operators shall not terminate miners who violate the mine operator's policy for the first time (*e.g.*, by testing positive for alcohol or drugs). Rather, those miners testing positive for the first time, who have not committed some other separate terminable offense, shall be provided job security while the miner seeks appropriate evaluation and treatment. The miner will be able to be reinstated and allowed to resume performance of safety-sensitive job duties provided the miner complies with return-to-duty requirements outlined in §§ 66.405 and 66.406.

(c) For subsequent violations of the mine operator's alcohol- and drug-free mine policy, the mine operator shall specify appropriate disciplinary steps, up to and including termination. At a minimum, miners shall not be allowed to perform safety-sensitive job duties until such time that they have satisfactorily complied with the return-to-duty process as specified in §§ 66.405 and 66.406 of this rule.

§ 66.401 Operator actions pending receipt of test results.

(a) Miners who have been selected for random testing shall be returned to duty immediately following the test and while awaiting the results.

(b) Miners who have been tested for alcohol and/or drugs based on reasonable suspicion or because the mine operator has determined that they may have contributed to an accident may be suspended from performance of safety-sensitive job duties until the verified test results have been received.

(c) All miners suspended from performing safety-sensitive job duties pending results should be treated in the same manner with respect to this rule and no action adversely affecting the miner's pay and benefits shall be taken pending the verified outcome of the testing process.

(d) In the event that a miner does not work at all during the suspension period (*i.e.*, the miner is not assigned non-safety-sensitive job duties) and the test result is verified positive, mine operators may choose to withhold pay for the suspension period in accordance with mine operator policy and/or any existing labor-management agreement.

§ 66.402 Substantiating legitimate use of otherwise prohibited substances.

Although mine operators shall not receive test results until after an MRO has verified them, mine operators must ensure miners have adequate opportunity to demonstrate that their use of prescription drugs is legitimately authorized. However, possession of a valid prescription from a medical professional in and of itself may not constitute sufficient proof of legitimate and appropriate use. It is the

responsibility of the MRO to make this determination. If the miner asserts that the presence of a drug or drug metabolite in his/her specimen results from taking prescription medication, the MRO must review and take all reasonable and necessary steps to verify the authenticity of all medical records the miner provides. The MRO may contact the miner's physician or other relevant medical personnel and/or direct the miner to undergo further medical evaluation.

§ 66.403 Operator actions after receiving verified test results.

(a) A mine operator who receives a verified positive drug test result or a verified adulterated or substituted drug test result must immediately remove the miner involved from performing safety-sensitive job duties and refer the miner to a qualified SAP. Action must be taken upon receiving the initial report of the verified test result. A mine operator must not wait to receive the written report or the result of a split specimen test.

(b) A mine operator who receives a blood alcohol concentration test result of 0.04 percent or higher must immediately remove the miner involved from performing safety-sensitive job duties and refer the miner to a qualified SAP. A mine operator must not wait to receive the written report of the result of the test.

(c) A mine operator must not alter an alcohol or drug test result transmitted by a MRO or BAT.

(d) In the event that the MRO verifies that a test is negative or cancels the test:

(1) The miner will be immediately returned to the performance of safety-sensitive job duties if he/she has been removed based on reasonable suspicion;

(2) The miner will suffer no adverse personnel consequences or loss in pay; and

(3) No individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result will be retained. The record of the test will reflect that it was a negative test.

§ 66.404 Evaluation and referral.

(a) A miner who has failed a test for prohibited substances or refused or adulterated a test cannot perform safety-sensitive job duties until a SAP evaluation has been completed and the miner successfully complies with the SAP's recommendations for education and/or treatment.

(b) Mine operators must provide to each such miner (including an applicant or new miner) a listing of SAPs available to the miner and acceptable to the mine operator. This listing should include the names, addresses, and telephone numbers of the available SAPs. The miner may avail himself or herself of the services of the SAP to receive an evaluation and referral for treatment. The miner shall be allowed to return to performance of safety-sensitive job duties following a first-violation violation and provided the miner complies with the return-to-duty and follow-up testing provisions found in §§ 66.405 and 66.406.

(c) The SAP's recommendation for assistance will serve as a referral source to assist the miner's entry into an education and/or treatment program.

(d) Miners who have failed or refused an alcohol or drug test may not seek a second SAP's evaluation in order to obtain a different recommendation, nor may a mine operator do so if the miner has already been evaluated by a qualified SAP. If the miner, contrary to this paragraph, has obtained a second SAP evaluation, mine operators may not rely on it for any purpose under this part. Only the SAP who made the initial evaluation may modify his or her initial evaluation and recommendations based on new or additional information (*e.g.*, from an education or treatment program).

(e) While the SAP's referral shall always be made at the miner's first offense, employers may choose to offer additional opportunities for treatment and return-to-work, but must do so in a way that is uniform and consistent.

§ 66.405 Return-to-duty process.

(a) After miners testing positive for alcohol or drugs are assessed by a SAP and follow that SAP's educational or treatment recommendations, they may return to safety-sensitive job duties upon submitting to return-to-duty and follow-up testing as described in §§ 66.406.

(b) SAPs must re-evaluate the miner to determine if the miner has successfully carried out the recommended education and/or treatment so that the mine operator can decide whether to return the miner to safety-sensitive job duties.

(c) Should a SAP provide written notice that the miner has not successfully complied with the SAP's recommendations, the mine operator must not return the miner to the performance of safety-sensitive job duties and may take action consistent with company policy and/or labor-management agreements.

(d) Although the SAP can verify completion of or compliance with recommended treatment, it is the mine operator who decides whether to put the miner back to work in a safety-sensitive position. However a miner who has successfully completed the recommended treatment and passed the return-to-duty tests may not be discharged for his/her first offense.

§ 66.406 Return-to-duty and follow-up testing.

(a) Miners must have an alcohol test with a blood alcohol concentration of less than 0.04 percent and a negative return-to-duty drug-test result before resuming performance of safety-sensitive job duties.

(b) A mine operator shall conduct follow-up testing of each miner who returns to duty, as follows:

(1) A SAP is the sole determiner of the number and frequency of follow-up tests needed for a particular miner and whether these tests will be for alcohol, drugs, or both. If the miner had a positive drug test, but the SAP evaluation or the treatment program professional determines that the miner also has an alcohol problem, a SAP shall require that the miner have follow-up tests for both alcohol and drugs.

(2) A SAP must establish a written follow-up testing plan for each miner who has committed a violation of this rule, and who seeks to resume the performance of safety-sensitive job duties only after the miner has successfully complied with recommendations for education and/or treatment.

(3) At a minimum, a miner will be subject to six unannounced follow-up tests in the first 12 months of resuming safety-sensitive job duties. It is possible, however, that the SAP may require more than six unannounced follow-up tests, and that the testing be continued for up to 24 months after the miner resumed his/her safety-sensitive job duties.

(4) The mine operator may not impose additional testing requirements (*e.g.*, under company authority) on the miner that go beyond the SAP's follow-up testing plan.

(5) The mine operator must carry out the SAP's follow-up testing requirements and may not allow the miner to continue to perform safety-sensitive job duties unless follow-up testing is conducted as directed by the SAP. Mine operators failing to do so will be in violation of this rule.

(6) Mine operators have discretion in scheduling follow-up tests but must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the miner is given no advance notice.

(7) Other tests conducted (*e.g.*, those carried out under the random testing

program) cannot substitute for this follow-up testing requirement.

Subpart F—Recordkeeping and Reporting

§ 66.500 Recordkeeping requirements.

(a) Protection of employee records.

(1) Records of drug- or alcohol-test results received are confidential communications between the mine operator and the miner.

(2) If records are stored electronically, a mine operator must ensure that the records are secured.

(b) Mine operators must keep and retain the following test records for at least three years:

(1) The number of workers in safety-sensitive positions;

(2) The total number tested;

(3) The number of positive alcohol and drug tests for each substance; and

(4) A record of which miners were tested, the dates of their tests, their test results, and return-to-duty and follow-up test results; these records should be retained separately from aggregate data on violations and violation rates.

(c) In addition, mine operators are required to:

(1) Include post-accident test results in accident reports regardless of whether the test(s) are positive or negative.

(2) Annually compute and retain records of the percentage of positive random alcohol and drug tests.

(d) MSHA inspections:

(1) Mine operators' alcohol- and drug-free workplace policies and program descriptions should be made available to MSHA inspectors upon their request; however, this rule does not require routine review of alcohol- and drug-free workplace programs by MSHA inspectors.

(2) Any and all alcohol- or drug-test results will be made available upon request of MSHA inspectors or investigators and will be used in assessing overall compliance with safety regulations as well as in determining the cause of accidents.

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Part VI

Department of Housing and Urban Development

24 CFR Part 1003

Prohibition on Use of Indian Community Development Block Grant Assistance for Employment Relocation Activities; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1003

[Docket No. FR–5115–P–01]

RIN 2577–AC78

Prohibition on Use of Indian Community Development Block Grant Assistance for Employment Relocation Activities

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend HUD's regulations for the Indian Community Development Block Grant (ICDBG) program by prohibiting Indian tribes and Alaska Native villages from using ICDBG funds to facilitate the relocation of for-profit businesses from one labor market area to another, if the relocation is likely to result in significant job loss. The proposed rule would prohibit Indian tribes and Alaska Native villages from using ICDBG funds for ''job pirating'' activities that are likely to result in significant job loss. ''Job pirating,'' in this context, refers to the use of ICDBG funds to lure or attract a business and its jobs from one community to another. To prevent the rule from having an effect in situations where the relocation of a business causes an insignificant loss of jobs, the proposed rule would provide that a loss of 25 or fewer jobs from an area, as a result of an ICDBG-funded economic development project, would not constitute a significant loss of jobs.

DATES: *Comment Due Date:* November 7, 2008.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel (OGC), Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0001.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that Web site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule. *No Facsimile Comments.* Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. eastern time weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division, OGC, at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Deborah Lalancette, Director, Office of Grants Management, Office of Native American Programs, 1670 Broadway, 23rd Floor, Denver, CO 80202, telephone number (301) 675–1600 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the Federal Information Relay Service toll-free number at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Title I of the Housing and Community Development Act of 1974, as amended, (42 U.S.C. 5301–5320) (1974 HCD Act) establishes the statutory framework for the Community Development Block Grant (CDBG) program. Section 106(a)(1) of the 1974 HCD Act authorizes grants to Indian tribes for the ICDBG program. HUD's regulations implementing the ICDBG program are located at 24 CFR part 1003 (entitled ''Community Development Block Grants for Indian Tribes and Alaska Native Villages''). The purpose of the ICDBG program is the development of viable Indian and Alaska Native communities, including the creation of decent housing, suitable living environments, and economic opportunities primarily for persons with low and moderate incomes. Grantees may use their ICDBG funds for activities authorized by section 105(a) of the 1974 HCD Act.

Section 588 of the Quality Housing and Work Responsibility Act of 1998 amended section 105 of the 1974 HCD Act (42 U.S.C. 5305). Specifically, section 588 added to section 105 a new subsection (h) entitled ''Prohibition on Use of Assistance for Employment Relocation Activities.'' This subsection prohibits the use of CDBG funds to facilitate the relocation of for-profit businesses from one labor market area to another, if the relocation is likely to result in significant job loss. Subsection (h) states:

> (h) Prohibition on Use of Assistance for Employment Relocation Activities—Notwithstanding any other provision of law, no amount from a grant under section 106 made in fiscal year 1999 or any succeeding fiscal year may be used to assist directly in the relocation of any industrial or commercial plant, facility, or operation, from 1 area to another area, if the relocation is likely to result in a significant loss of employment in the labor market area from which the relocation occurs.

Applicants for ICDBG grants have been notified of this statutory requirement in annual Notices of Funding Availability.

II. This Proposed Rule

This proposed rule would implement subsection (h) of the 1974 HCD Act by revising HUD's ICDBG program regulations in 24 CFR part 1003. The proposed rule would establish a new § 1003.209 (entitled ''Prohibition on Use of Assistance for Employment Relocation Activities''), which would describe the ICDBG job-piracy provisions. This proposed rule would also amend § 1003.505 (entitled ''Records to be Maintained''), to ensure that appropriate recordkeeping requirements are met.

III. Significant Features of the Proposed Rule

A. *Direct assistance to for-profit businesses.* Section 105(a)(17) of the 1974 HCD Act authorizes ICDBG recipients to provide direct assistance to for-profit businesses for economic development activities. Additionally, section 105(a)(15) authorizes recipients

to provide ICDBG funds to Community Based Development Organizations (CBDOs) for economic development activities that increase economic opportunities, or that stimulate or retain businesses or permanent jobs.

In accordance with the statutory language of section 105(h), the proposed rule would prohibit the provision of ICDBG assistance to for-profit businesses (including business expansions) under sections 105(a)(15) and 105(a)(17) of the 1974 HCD Act, if:

(1) The funding will assist in the relocation of a plant, facility, or operation; and

(2) If the relocation is likely to result in a significant loss of jobs in the area from which the relocation occurs.

The proposed rule would not cover the business activities of nonprofit entities. HUD believes that the likelihood of ICDBG assistance to a not-for-profit business relocation is limited.

B. *Definition of ''area.''* The statutory language of section 105(h) prohibits the relocation of any industrial or commercial plant, facility, or operation, from ''one area to another,'' if the relocation is likely to result in significant job loss. HUD believes the relevant definition of labor market ''area'' for a Native American economic development project is the ''Identified Service Area'' for the eligible applicant, as defined in 24 CFR 1003.4.

C. *Definition of ''operation.''* Section 105(h) prohibits the use of ICDBG assistance with respect to the relocation of any industrial or commercial plant, facility, or ''operation'' from one Identified Service Area to another. This proposed rule would define the term ''operation'' to include, but not be limited to, any equipment, position, employment opportunity, production capacity, or product line.

D. *Determining ''significant loss of jobs.''* Section 105(h) prohibits ICDBG assistance for business relocation activities that ''will result in a significant loss of employment'' in the Identified Service Area from which the relocation occurs. This proposed rule would require that an ICDBG grantee, in determining whether a significant job loss would occur, collect labor force statistics for the Identified Service Area where the business is located before the relocation occurs. The grantee also would be required to document the number of jobs that the business plans to relocate to the new Identified Service Area.

In a large Identified Service Area, a job loss of one-tenth of one percent of the total labor market may constitute a large number of employees. Therefore, this proposed rule would provide that in all cases a loss of more than 500 jobs will be considered to constitute a significant job loss. To prevent the rule from having an effect in situations where the relocation of a business causes an insignificant loss of jobs, the proposed rule would provide that a loss of 25 or fewer jobs from an Identified Service Area, as a result of an ICDBG-funded economic development project, would not constitute a significant loss of jobs.

In summary, a loss of 25 or fewer jobs as a result of a single activity will not constitute a significant job loss; any loss greater than 500 will continue to be counted as significant; and job losses between 25 and 500 must be less than 0.1 percent of the Identified Service Area's labor force to avoid being counted as significant.

E. *Activities and businesses exempt from the job piracy prohibition.* Under the proposed rule, certain activities and businesses would be exempt from the job piracy prohibition. This proposed rule would not apply to relocation assistance required by the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601-4655) (implemented at 24 CFR part 42) (URA) and, with respect to the ICDBG regulations at 24 CFR 1003.602, microenterprises and assistance to businesses that buy equipment and/or inventory in arms-length transactions and move the equipment and/or inventory to another Identified Service Area.

1. *Uniform Relocation Act and related assistance.* HUD proposes to exclude relocation assistance required to be provided to a business under the URA. Businesses that receive such assistance and are required to relocate generally are not voluntarily relocating. In addition, relocation assistance under section 105(a)(11), as implemented at §§ 1003.201(h) and 1003.602(b), (c), and (d), should be excluded for the same reasons. HUD does not believe that the anti-pirating provisions were intended to prevent businesses that are forced to relocate as a result of a government action covered by the URA from relocating to another Identified Service Area.

2. *Microenterprises.* HUD considered whether microenterprises should be subject to the job pirating restrictions, but has determined that this type of business was not the intended target of the statutory prohibition. Microenterprises, generally, have five or fewer employees and typically do not seek resources to relocate jobs to other areas.

3. *ICDBG-assisted arms-length transactions.* The exemption for businesses that buy equipment, inventory, or other physical assets in arms-length transactions is meant to protect assisted businesses that merely purchase equipment and inventory that are located in one Identified Service Area and move them to a new location. The job piracy prohibition targets businesses that move existing operations from one labor market area to another.

This proposed rule would apply to ICDBG assistance to a business that: (a) Shuts down or downsizes a facility and sells the equipment in a non-arms-length transaction (an example of a non-arms-length transaction is a firm selling equipment to a subsidiary); or (b) sells, in an arms-length transaction, an interest in an existing business, product line, customer base, or the entire stock-in-trade and goodwill of an existing business.

This proposed rule would not apply to assistance to a business that only purchases used equipment in an arms-length transaction. HUD believes that the sale and purchase of equipment, inventories, or other business assets on the open market were not intended to be included under the business relocation provisions of section 105(h).

F. *Documentation requirements for ICDBG recipients and businesses.* This proposed rule would require that, for each ICDBG-assisted business covered by this rule, the recipient's ICDBG project file must document: Whether the business has a plant, facility, or operation in an area outside of the recipient's Identified Service Area; and, if the business has one or more plants, facilities, or operations located in other areas, whether the business plans to relocate jobs from other locations to the site being assisted with ICDBG funds. Prior to a decision to provide ICDBG assistance to a business that has a plant, location, or facility in other areas, the recipient shall document whether the number of jobs relocated by the business at each of the locations that is losing jobs to the new facility would constitute a significant job loss, as defined in this rule. If the recipient decides to commit ICDBG assistance to a business, then it must require and obtain, as a condition for assistance, a certification from the assisted business that neither it, nor any of its subsidiaries, has plans to relocate jobs, at the time the agreement is signed, that would result in a significant job loss, as defined in this rule. The business must provide this certification to the recipient as a part of the agreement committing ICDBG assistance to the business.

IV. Tribal Consultation

HUD's policy is to consult with Indian tribes early in the rulemaking process on matters that have tribal implications. Accordingly, HUD sent letters to all eligible funding recipients under the ICDBG program informing them of the nature of the forthcoming rule and soliciting comments. The Department received one response to the consultation request, expressing full support for the proposed regulatory change. In addition, tribes have the opportunity to comment on this proposed rule, and HUD welcomes such comment.

V. Findings and Certifications

Paperwork Reduction Act

The information collection requirements contained in this rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

The burden of the information collections in this proposed rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Section reference	Number of parties	Number of responses per respondent	Estimated average time for requirement (in hours)	Estimated annual burden (in hours)
§ 1003.209 & § 1003.505	15 plus	1	3	45

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Comments must refer to the proposal by name and docket number (FR–5115–P–01) and must be sent to:

HUD Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax number: (202) 395–6974; and

Ms. Sherry Fobear-McCown, Office of Public and Indian Housing, U.S. Department of Housing and Urban Development, Room 4116, 451 Seventh Street, SW., Washington, DC 20410–5000.

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The Finding of No Significant Impact is available for public inspection between the hours of 8 a.m. and 5 p.m. eastern time, weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. There are no anti-competitive discriminatory aspects of the rule with regard to small entities and there are no unusual procedures that would need to be complied with by small entities. Accordingly, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, HUD is sensitive to the fact that the uniform application of requirements on entities of differing sizes often places a disproportionate burden on small businesses. Therefore, HUD specifically invites comments from all entities, including small entities, regarding less burdensome alternatives to this rule, that will meet HUD's objectives as described in this preamble.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Order. This proposed rule does not have federalism implications and would not impose substantial direct compliance costs on state and local governments nor preempt state law within the meaning of the Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This proposed rule does not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of the UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) number for the ICDBG program is 14.862.

List of Subjects in 24 CFR Part 1003

Alaska; Community development block grants; Grant programs—housing and community development; Grant programs—Indians; Indians; Reporting and recordkeeping requirements.

Accordingly, for the reasons discussed in the preamble, HUD proposes to amend 24 CFR part 1003 to read as follows:

PART 1003—COMMUNITY DEVELOPMENT BLOCK GRANTS FOR INDIAN TRIBES AND ALASKA NATIVE VILLAGES

1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 5301–5320.

2. Add § 1003.209 to read as follows:

§ 1003.209 Prohibition on use of assistance for employment relocation activities.

(a) *Prohibition.* ICDBG funds may not be used to directly assist a business, including a business expansion, in the relocation of a plant, facility, or operation from one Identified Service Area to another Identified Service Area, if the relocation is likely to result in a significant loss of jobs in the Identified Service Area from which the relocation occurs.

(b) *Definitions.* The following definitions apply to this section:

(1) *Directly assist.* Directly assist means the provision of ICDBG funds for activities pursuant to:

(i) § 1003.203(b); or

(ii) §§ 1003.201(a) through (d), 1003.201(k), 1003.203(a), or § 1003.204 when the grantee, subrecipient, or, in the case of an activity carried out pursuant to § 1003.204, a Community Based Development Organization (CBDO) enters into an agreement with a business to undertake one or more of these activities as a condition of the business relocating a facility, plant, or operation to the grantee's Identified Service Area. Provision of public facilities and indirect assistance that will provide benefit to multiple businesses does not fall under the definition of ''directly assist,'' unless it includes the provision of infrastructure to aid a specific business that is the subject of an agreement with the specific assisted business.

(2) *Area.* The relevant definition of ''area'' for a Native American economic development project is the ''Identified Service Area'' for the eligible applicant, as defined in § 1003.4.

(3) *Operation.* A business operation includes, but is not limited to, any equipment, employment opportunity, production capacity, or product line of the business.

(4) *Significant loss of jobs.* (i) A loss of jobs is significant if the number of jobs to be lost in the Identified Service Area in which the affected business is currently located is equal to or greater than one-tenth of one percent of the total number of persons in the labor force of that area; or, in all cases, a loss of 500 or more jobs. Notwithstanding the aforementioned, a loss of 25 jobs or fewer does not constitute a significant loss of jobs.

(ii) A job is considered to be lost due to the provision of ICDBG assistance if the job is relocated within 3 years of the provision of assistance to the business; or the time period within which jobs are to be created as specified by the agreement between the business and the recipient, if it is longer than 3 years.

(c) *Written agreement.* Before directly assisting a business with ICDBG funds, the recipient, subrecipient, or a CBDO (in the case of an activity carried out pursuant to § 1003.204) shall sign a written agreement with the assisted business. The written agreement shall include:

(1) *Statement.* A statement from the assisted business as to whether the assisted activity will result in the relocation of any industrial or commercial plant, facility, or operation from one Identified Service Area to another, and, if so, the number of jobs that will be relocated from each Identified Service Area; and

(2) *Required certification.* If the assistance will not result in a relocation covered by this section, a certification from the assisted business that neither it, nor any of its subsidiaries, has plans to relocate jobs, at the time the agreement is signed, that would result in a significant job loss as defined in this rule.

(d) *Assistance not covered by this section.* This section does not apply to:

(1) *Relocation assistance.* Relocation assistance under § 1003.602(b), (c), or (d);

(2) *Microenterprises.* Assistance to microenterprises as defined by section 102(a)(22) of the Housing and Community Development Act of 1974; and

(3) *Arms-length transactions.* Assistance to a business that purchases business equipment, inventory, or other physical assets in an arms-length transaction, including the assets of an existing business, provided that the purchase does not result in the relocation of the sellers' business operation (including customer base or list, goodwill, product lines, or trade names) from one Identified Service Area to another Identified Service Area and does not produce a significant loss of jobs in the Identified Service Area from which the relocation occurs.

3. Revise § 1003.505 to read as follows:

§ 1003.505 Records to be maintained.

Each grantee shall establish and maintain sufficient records to enable the Secretary to determine whether the grantee has met the requirements of this part. This includes establishing and maintaining records demonstrating that the recipient has made the determinations required as a condition of eligibility of certain activities, including as prescribed in § 1003.209.

Dated: May 1, 2008.

Paula O. Blunt,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. E8–20785 Filed 9–5–08; 8:45 am]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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44	(869–062–00180–1)	50.00	Oct. 1, 2007
45 Parts:			
1–199	(869–062–00181–9)	60.00	Oct. 1, 2007
200–499	(869–060–00182–7)	34.00	[9] Oct. 1, 2007
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1200–End	(869–062–00184–3)	61.00	Oct. 1, 2007
46 Parts:			
1–40	(869–062–00185–1)	46.00	Oct. 1, 2007
41–69	(869–062–00186–0)	39.00	Oct. 1, 2007
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47 Parts:			
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48 Chapters:			
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2005, through January 1, 2006. The CFR volume issued as of January 1, 2005 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2007. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2006 through April 1, 2007. The CFR volume issued as of April 1, 2006 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2006, through July 1, 2007. The CFR volume issued as of July 1, 2006 should be retained.

[8] No amendments to this volume were promulgated during the period October 1, 2005, through October 1, 2007. The CFR volume issued as of October 1, 2005 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2006, through October 1, 2007. The CFR volume issued as of October 1, 2006 should be retained.